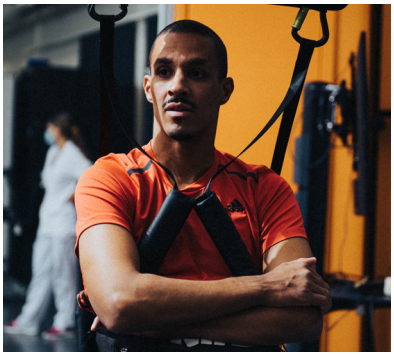
# 2022 Annual Report



ONWARD®

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***In this Annual Report 'ONWARD', 'the Company', 'the Group', 'we', 'us' and 'our' are used interchangeably to refer to ONWARD Medical N.V. and/or any of its subsidiaries, in general or where no useful purpose is served by identifying the particular company***

***European single electronic reporting format (ESEF) and PDF version***

*This is a copy of the annual financial report of ONWARD Medical N.V. for the year ended 31 December 2022. This version has been prepared for ease of use and does not contain ESEF information as specified in the Regulatory Technical Standards on ESEF (Delegated Regulation (EU) 2019/815). The official The official ESEF reporting package is available on our website at* ***this link.***

# ONWARD at a Glance

- Founded in 2015
- 100 employees
- HQ in Eindhoven, the Netherlands
- Science and Engineering Center in Lausanne, Switzerland
- Growing US presence in Boston, Massachusetts
- IPO 2021, Euronext Brussels and Amsterdam; EUR 150M+ raised since inception

- Technology – 2 purpose-built neuromodulation platforms that stimulate the spinal cord via implantable (ARC$^{IM}$) or external (ARC$^{EX}$) technologies
- Innovation – 8 FDA Breakthrough Device Designations and >330 issued or pending patents
- Clinical validation – One pivotal trial completed with positive top-line results reported for ARC$^{EX}$; positive interim outcomes also reported for ARC$^{IM}$ blood pressure indication
- Commercialization - Large total available market (EUR 20B+); first commercial sale expected late 2023; deep pipeline; favorable reimbursement; strategic relationship with Christopher & Dana Reeve Foundation

# Message from the Chairman & CEO

Dear Shareholders, Colleagues, Partners, and Collaborators,

2022 was an important and eventful year for ONWARD, filled with achievements and milestones across our range of activities.

We continued to advance our scientific understanding, validated by publications in leading peer-reviewed journals and fueled by grant awards to support our progress in developing therapies for mobility, upper extremity movement, and the use of brain-computer interfaces. We completed development of our ARC$^{IM}$ IPG, a purpose-designed neurostimulator. We added 24 new patents, bringing our total of issued or pending patents to over 330 worldwide. And we made excellent progress in the conduct of clinical studies, reporting positive top-line data from our first pivotal study (Up-LIFT), positive observational data from the LIFT Home study, and positive outcomes data from the first 10 participants using our ARC$^{IM}$ Therapy to better regulate low blood pressure after spinal cord injury. Perhaps most importantly, we continued to strengthen our Board of Directors and Leadership Team, adding several highly capable leaders to help grow the company to its full potential.

As we shared last year, it is a privilege to lead this company with its many wonderful employees, research collaborators, and business partners. Our work is important and meaningful, and together we are focused on making a difference in the lives of people with spinal cord injury (SCI).

For those of you who are learning about ONWARD for the first time, we are here to address an important and prevalent problem. Nearly 7,000,000 people worldwide have spinal cord injury[1]. While most people associate SCI with paralysis and loss of sensation, there are often other accompanying challenges such as infection, incontinence, pressure sores, poor blood pressure regulation, and loss of sexual function. The quality of life following spinal cord injury can be quite poor for the injured and their caregivers. SCI is also an expensive condition, with the average lifetime cost of care exceeding EUR 2.2M for someone with paraplegia and EUR 4.4M for someone with tetraplegia[2].

Conventional rehabilitation does not provide adequate benefit, with most people reaching a plateau in their progress after three to six months. Thereafter, many of those injured face decades of continuing challenges, declines in quality of life, and dependence on outside care. ONWARD seeks to solve this unmet need by delivering durable therapies that can improve strength, function, and quality of life, even for those injured many years ago.

## Our Vision

**Empowered by movement, people with spinal cord injury will enjoy life in every way that matters to them.**

Our team is pursuing this vision with urgency and determination, developing ARC Therapy with the intent to commercialize and make our solutions broadly available starting late 2023 in the United States and Europe. We have two technology platforms, one external (called ARC$^{EX}$) and the other implantable (called ARC$^{IM}$).

The work to complete and commercialize these platforms is aided by eight FDA Breakthrough Device Designation awards and protected by more than 330 issued or pending patents worldwide. While many of these innovations were created by our innovative R&D team, others have been exclusively licensed from the top neuroscience research universities around the world, underscoring ONWARD as a pioneer and a leader in our space.

## Message from the Chairman & CEO

Benefitting from our successful initial public offering on Euronext in late 2021, we remain well capitalized and focused on fulfilling our vision to help people with spinal cord injury in their activities of daily life. We pledge to be good stewards of this capital and hope both new and existing investors enjoy good returns, financial and otherwise, from this journey you have undertaken alongside us.

We are aided in our pursuits by our many strong relationships with SCI advocacy groups across the globe, such as the Christopher and Dana Reeve Foundation in the United States. We are grateful for these partnerships and the insights they provide.

We are proud of our many achievements in 2022 and we have an ambitious set of goals for 2023 and beyond. Please sign up for updates on our website or follow ONWARD on social media so we can keep you well informed of our progress throughout the year.

Warm regards,

**Jan Øhrstrøm & Dave Marver**

**Jan Øhrstrøm**
Chairman

**Dave Marver**
CEO

*[1]Kumar et al. 2018, "Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume", World Neurosurg., vol. 113, pp. e345-e363, May 2018, doi: 10.1016/j.wneu.2018.02.033.*
*[2]2020 NSCISC Annual Report, US*

# Achievements

## Science

Together with our research partners at École polytechnique fédérale de Lausanne (EPFL), Lausanne University Hospital (CHUV) and .NeuroRestore we continued to make remarkable progress in the quest to develop therapies to help people with SCI as well as those living with other movement disabilities, such as Parkinson's disease.

- In February, the Company's technology was leveraged to enable people with the most severe form of spinal cord injuries to stand and walk again. This breakthrough was published in the journal *Nature Medicine* and highlighted in major media outlets around the globe.
- In April, the *New England Journal of Medicine* highlighted the use of the Company's innovative approach to treating orthostatic hypotension (low blood pressure) in a patient with MSA-P, a form of Parkinson's disease that affects the sympathetic nervous system.
- In June, research published in *Nature Neuroscience* demonstrated the potential for ONWARD ARC$^{IM}$ Therapy to restore movement and function in hands and arms after spinal cord injury.
- In November, ONWARD and our research partners at EPFL and CEA-Clinatec were awarded a second grant from the European Innovation Council to further develop an innovative Brain-Computer Interface (BCI) technology for restoring mobility and upper limb function in people with spinal cord injury. The grant will fund integration between our implanted ARC$^{IM}$ system, which delivers targeted, programmed stimulation of the spinal cord, and Clinatec's WIMAGINE, an implantable device that records and decodes the brain's cortical signal to predict a person's intention to move. We believe the development of a BCI platform has the potential to make ONWARD therapies even more effective as we proceed to 2$^{nd}$ and 3$^{rd}$ generations of our system.

  The Company also announced that it was the First Place Winner of the 2022 Brain-Computer Interface (BCI) Award. The award was granted to ONWARD and several research partners for their submission, "Walking naturally after spinal cord injury using a brain-spine interface." This application focused on the work being done under the Reverse Paralysis project to develop a fully implantable BCI to help people walk more naturally after spinal cord injury with the benefit of ONWARD ARC Therapy. The International BCI Award is given by the BCI Award Foundation and is one of the top accolades recognizing outstanding and innovative research in this field. In 2022, more than 100 projects were submitted, and only 12 finalists selected, including teams from Stanford University and the University of California San Francisco.
- In November, the Company's research partners from EPFL and CHUV published pioneering research in Nature, in which they identified the precise neurons that restore walking after paralysis. This paper detailed the results from 9 participants in the STIMO trial, all of whom were able to stand and walk with the benefit of ARC Therapy.

### Intellectual Property

The Company added 24 patents to its formidable IP portfolio, now totaling over 330 issued and pending patents. We also obtained option rights to license intellectual property from EPFL and CHUV, which allows the Company to develop and commercialize a novel Brain-Computer Interface, that captures brain signals and triggers spinal cord stimulation to restore voluntary control over paralyzed limbs. These rights also support the development and commercialization of therapies to alleviate gait disorders (freezing of gait, etc.) in people with Parkinson's disease by stimulating the spinal cord.

### Innovation & Clinical Development

- In May 2022, the first participant was enrolled in the HemON feasibility study, a precursor to the upcoming planned pivotal trial with ARC$^{IM}$ for blood pressure, a study called EMPOWER BP. This was the first human use of the ONWARD ARC$^{IM}$ implantable pulse generator (IPG). This purpose-built IPG delivers targeted electrical stimulation precisely to the areas of the spinal cord responsible for triggering or controlling movement and autonomic functions that may be affected by a spinal cord injury or neurodegenerative disorder.
- In September, we achieved a very important milestone, reporting positive top-line results from our Up-LIFT pivotal study evaluating ARC$^{EX}$ Therapy. The study enrolled 65 people at 14 leading SCI centers in the US, Europe, and Canada, and achieved its primary effectiveness endpoint of improvement in upper extremity strength and function in people with SCI. With these important results, the Company is preparing to submit for regulatory approval in both the US and Europe.
- In October, we released data from the LIFT Home observational study, which evaluated the feasibility and safety of ARC$^{EX}$ Therapy when used at home. Participants performed training on activities of daily living three times per week over a one-month period. Approximately 97% of these sessions were completed without usability issues, supporting the feasibility of home-based treatment.
- During 2022 and early 2023, we added five more Breakthrough Device Designations (BDD), bringing our total to eight BDDs for ARC Therapy. The FDA's Breakthrough Device program is designed to help patients and their physicians receive timely access to innovative technologies that have the potential to provide more effective treatment or diagnosis for debilitating conditions of great unmet need, such as SCI. The FDA will provide ONWARD with priority review and the opportunity to interact with their experts throughout the premarket review phase. In short, we are hopeful these designations result in faster access to these important therapies.
- In December, we reported positive interim clinical outcomes from the first ten people treated to regulate blood pressure with implantable ARC Therapy, including HemON study participants. ARC$^{IM}$ Therapy immediately improved blood pressure levels in all study participants, who also reported improved quality of life, increased energy and vitality, and reduced dizziness. Based on these promising interim outcomes, we are preparing to initiate further clinical trials to include U.S. participants in 2023.


ONWARD
ARC IM


ARC IM

## Corporate

We continued to enhance our organizational capabilities and augment our leadership team in preparation for commercialization of our initial therapy, expected late 2023. The Company also enhanced its visibility in the financial markets:

- In March, the Company was added to Euronext Brussels' Bel-Small Index.
- In March, the Company confirmed its expectation that it had sufficient cash runway through the end of 2024.
- In April, Bryan, Garnier & Co, a leading investment bank focused on growth companies, initiated research coverage on the Company.
- In 2022 and early 2023, we welcomed several seasoned professionals to ONWARD, each with talent and experience to help us grow into our next phase as a commercial enterprise. Kristina Dziekan and Vivian Riefberg were added to our Board of Directors. Kristina formerly led international reimbursement and market access for Medtronic Neuromodulation and most recently served in a similar role at Alcon. Vivian retired in 2020 as a senior partner with McKinsey & Company, where she co-led their US healthcare practice and led their US government practice.
- We added Lara Smith Weber as CFO and Zouhir Mechta as VP Operations. After spending nearly 20 years in various finance leadership roles in Europe, Lara led the NASDAQ IPO for MorphoSys. Zouhir brings expertise gained during a long career in operations leadership for J&J and Dentsply Sirona.
- In early 2023, we further strengthened our leadership team with the hiring of Erika Ross as VP Global Clinical & Regulatory and Sarah Moore as VP Global Marketing. Erika joined from Abbott Neuromodulation, where she led clinical activities for their neuromodulation franchise, and was previously at Cala Health, where she managed the scientific research program that led to de novo clearance and launch of the company's neurostimulation technology. Sarah joined from Nevro, an implantable neuromodulation company, where she served as Head of Commercial Marketing. Prior to that, she held various leadership roles in global marketing across multiple J&J medical device franchises.

## Forward-Looking Information / Statements

This document contains certain forward-looking statements with respect to the financial condition, results of operations and business of ONWARD and certain of the plans and objectives of ONWARD with respect to these items. In particular, the words 'expect', 'anticipate', 'estimate', 'may', 'should', 'could', 'would', 'believe', 'outlook', 'potential', 'will', 'planned', 'pipeline', 'seek' and similar expressions are intended to identify forward-looking statements. By their nature, forward-looking statements involve risk and uncertainty because they relate to events and depend on circumstances that will occur in the future.

Actual results may differ materially from those expressed in these forward-looking statements, and you should not place undue reliance on them. For a discussion of factors that could cause future results to differ from such forward-looking statements, see also the Risk management and control of this Annual Report. For this reason, we can offer no assurances that the forward-looking statements published here will prove correct at a future date, and ONWARD assumes no duty to update any such forward-looking statements.

# Overview

At ONWARD, our mission is to enable people with spinal cord injury (SCI) to regain movement and other bodily functions so they can enjoy life in every way that matters to them. We develop and plan to commercialize therapies that address major challenges faced by people with SCI, leveraging the Company's ARC$^{IM}$ and ARC$^{EX}$ platforms to address a broad spectrum of injury locations and impairment severities. While our primary objective is to serve the needs of people with SCI, we envision that our therapies may also benefit other populations with similar challenges, such as people who have suffered stroke or who have Parkinson's disease or other neurodegenerative disorders. We also aim to reward those who invest their capital, time, and ideas in our Company, while engaging in sustainable, equitable, and inclusive business practices.

**The Case for Innovative Therapies**

Seven million people worldwide have an SCI, and the annual global incidence of new injuries exceeds 768,000. In the US and Europe alone, approximately 650,000 people live with SCI, and the annual incidence of new cases is about 50,000 (31,800 in Europe and 18,000 in the US).

SCI results not only in disability, decreased quality of life and poor health for individuals, but also in significant costs for economies, due to lost productivity and high healthcare costs. The average lifetime cost to support a person with a severe SCI can exceed USD 5M. Injuries to the spinal cord occur primarily as a result of automobile accidents and falls, and disproportionately affect young men.

# Market

## A large unmet medical need

**US**

Prevalence
**299,000[1]**

Incidence
**18,000[1]**

**Europe**

Prevalence
**352,000[2]**

Incidence
**31,800[3]**

[1]*2022 NSCISC Annual Statistical Report Complete Public Version*
[2]*European prevalence calculated by annual Incidence* 25 years of additional lifetime expectancy*
[3]*Kumar et al. 2018, Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume (traumatic spinal injury is broader than traumatic spinal cord injury).*

## Damage to the spinal cord resulting in loss of function

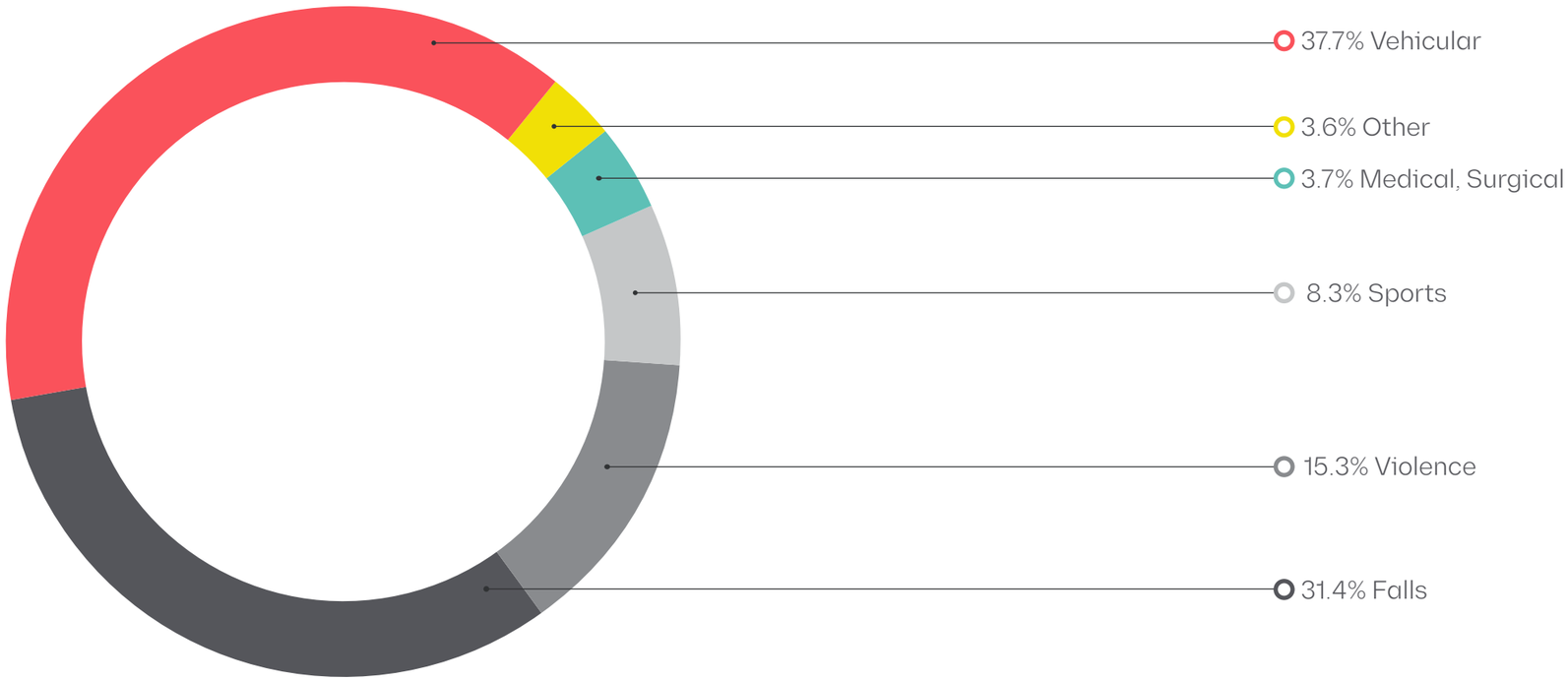
# SCI Causes & Patient Profile

### Profile of SCI Patient

- Nearly half of the injuries occur between the ages of 16 and 30 years[1]
- 78% of new SCI cases are male[1]

Currently, the neuromodulation market is comprised primarily of revenues from spinal cord stimulation for pain management and deep brain stimulation for Parkinson's disease, essential tremor, dystonia and epilepsy. The market is forecast to **reach USD 8.7 B by 2028 and is expected to grow to exhibit a CAGR of 12.5% over the same period.**

### SCI Causes




[1]*2022 NSCISC Annual Statistical Report Complete Public Version*

# Opportunity to create new segment, stimulating the spinal cord for movement and autonomic functions

ONWARD is pioneering a new segment within neuromodulation, by stimulating the spinal cord to restore mobility and autonomic functions in people with SCI, and potentially also those with stroke and Parkinson's disease.

Neurostimulation has emerged as a dynamic field for treatment of a range of clinical conditions

**$8.7B**[2] (2028E)

**12.5%CAGR** (2022 – 2028E)

Spinal cord stimulation and DBS are most well-developed current applications

**$2.9B**[2] (2019)

**8.0%CAGR** (2020 - 2026)

**Growth Trends:**

- Rising prevalence of neurological disorders
- Increasing capital availability
- Emergence of minimally invasive approaches

[2]*Sources: Global News Wire – Vantage Market Research, 2022; Fortune Business Insights Spinal Cord Stimulation Market; Harmsen I, E, Hasanova D, Elias G, J, B, Boutet A, Neudorfer C, Loh A, Germann J, Lozano A, M: Trends in Clinical Trials for Spinal Cord Stimulation. Stereotact Funct Neurosurg 2021;99:123-134 I 4 Johnson RL, Wilson CG. A review of vagus nerve stimulation as a therapeutic intervention. J Inflamm Res. 2018;11:203-213; Mayo Clinic*

# Neurostimulation Market

## FDA Approved

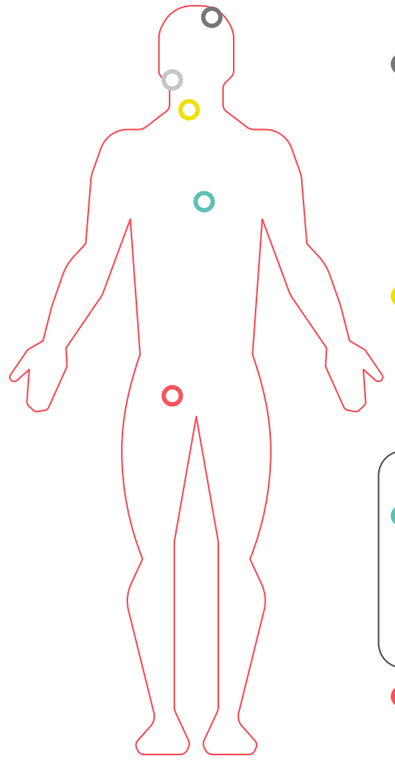
**Deep Brain Stimulation**
Dystonia, Epilepsy, Essential tremor, Obsessive-compulsive disorder, Depression, Parkinson's disease

**Hypoglossal Nerve Stimulation**
Sleep apnea

**Vagus Nerve Stimulation**
Depression, Epilepsy

**Spinal Cord Stimulation**
Pain management

**Sacral Nerve Stimulation**
Urinary incontinence, Fecal incontinence



## Emerging

**Deep Brain Stimulation**
Addiction, Chronic pain, Cluster headache, Dementia, Depression (major), Huntington's disease, MS, Stroke, Tourette, Traumatic brain injury, Sleep disorder, Autism

**Vagus Nerve Stimulation**
Alzheimer's, Obesity, Lung injury, Cardiovascular disease, Stroke, Diabetes, Anxiety, Pain management

**ONWARD Focus**

**Spinal Cord Stimulation**
Mobility, blood pressure control,bladder and bowel control, trunk control, upper limb function, sexual function, spasticity

**Sacral Nerve Stimulation**
Interstitial cystitis

# Our Strategy

Our strategy is to build an enduring, impactful, and successful medical device company that makes a meaningful difference in the lives of people with SCI and their loved ones.

- We work with leading neuroscience researchers across the globe to identify breakthrough therapies for people with SCI and other movement-related challenges.
- We leverage our R&D, clinical and regulatory capabilities to develop proprietary technologies that are well suited to deliver our breakthrough therapies at scale, and we protect these innovations via rigorous IP prosecution.
- We plan to commercialize these breakthrough therapies in our target markets, using a direct channel to SCI clinics and hospitals with functional neurosurgery expertise.

**Stages for the Execution of Our Strategy**

# Research & Preclinical Development

ONWARD has relationships with leading academic research centers throughout the world. The Company's primary relationship is with the company founders and their highly productive laboratory at .NeuroRestore, a research initiative of CHUV and EPFL. .NeuroRestore is led by Prof. Grégoire Courtine and neurosurgeon Dr. Jocelyne Bloch. In 2014, Prof. Courtine and Dr. Bloch co-founded ONWARD's predecessor entity alongside other researchers in neuroscience and neurosurgery. Prof. Courtine also serves as ONWARD's Chief Science Officer on a part-time basis.

Through its network of advanced research facilities in Switzerland, .NeuroRestore's research activities span the continuum from basic research to preclinical research to human proof-of-concept studies. Several projects with potential for commercialization have already progressed to the human proof-of-concept stage. ONWARD will select the most promising of these projects to develop and commercialize, based primarily on clinical results and commercial viability. The ARC$^{IM}$ platform can be leveraged for each of the indications with minor software and firmware modifications.

## Technology, research, and medical expertise across continuum of research stages

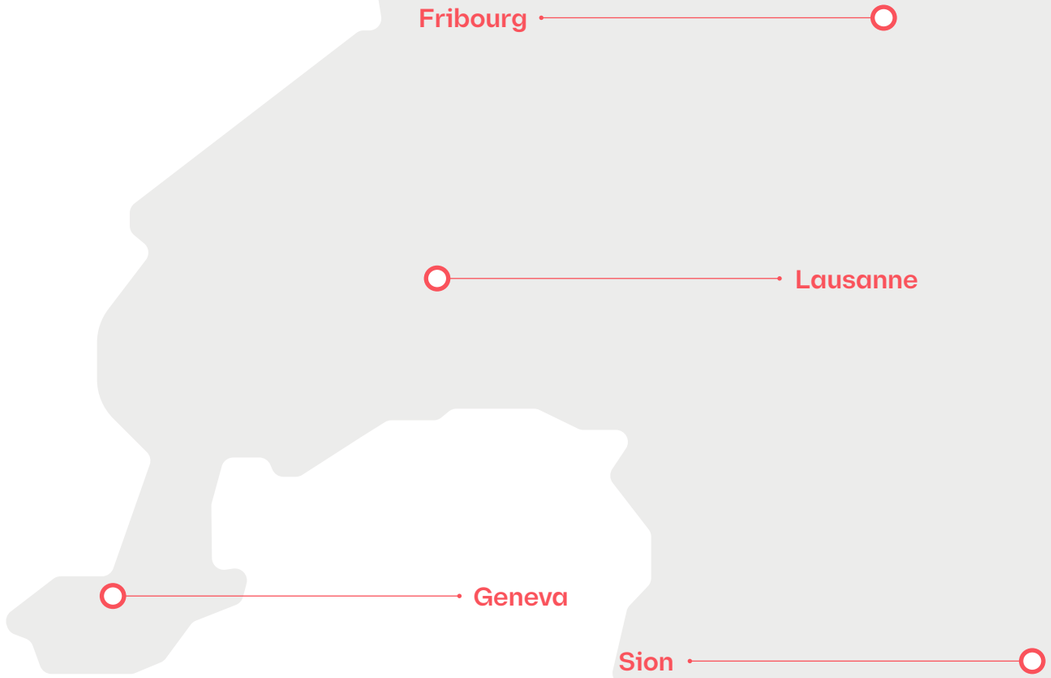
**CHUV – Lausanne**
University Hospital of Lausanne #9
worldwide Newsweek magazine

**EPFL – Geneva**
More than 2,000 scientists
#1 Neuroscience hub in Europe

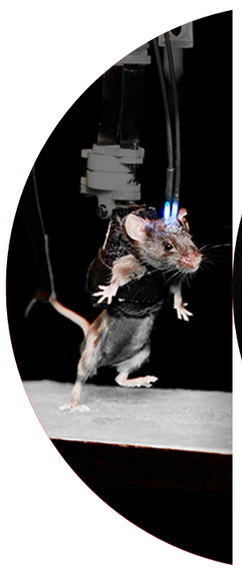
**Suva – Sion**
Specialized Center for
Acute Spinal Cord Injury

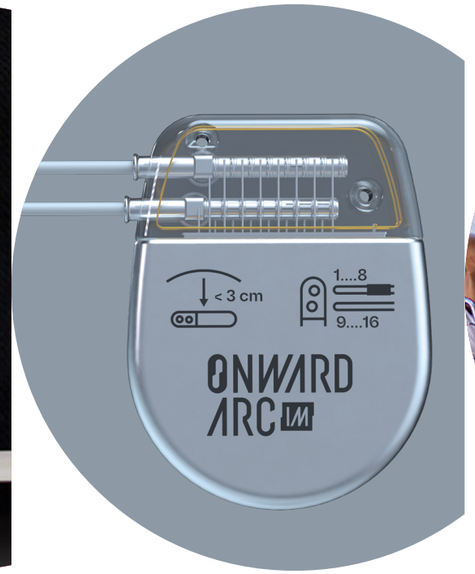
**UNIFR – Fribourg**
University of Fribourg
Pre-Clinical Center

# Network of Advanced Research Facilities



ONWARD | NeuroRestore






ONWARD

**Basic**
Mechanisms

**Preclinical**
Therapy

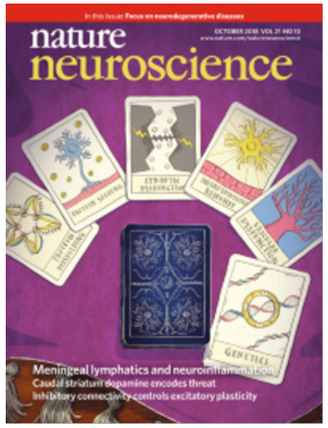
**Translation**
Scale Up

**Clinical**
Proof of Concept

**Commercial Engine**
Therapy

# High quality research underlies our therapies, validated by the caliber of .NeuroRestore's publications

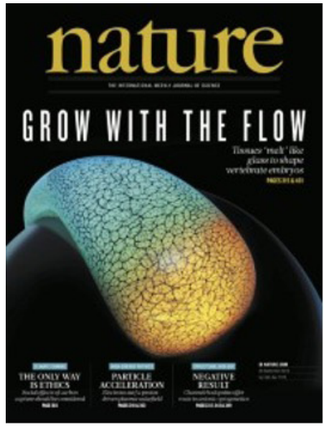
## Science

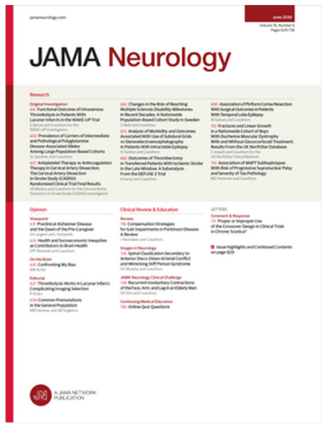














The .NeuroRestore team has published extensively in some of the most prestigious scientific journals. In 2018, Prof. Courtine and colleagues reported clinical results in Nature demonstrating, for the first time in humans, that motor control and the ability to walk continuously for at least 20 and up to 90 minutes could be restored even after complete paralysis[1]. These results were obtained using an implanted platform consisting of an implantable pulse generator (IPG) and an epidural lead. In February 2022, the team's latest results were published in *Nature Medicine*[2]. Three participants with complete sensorimotor SCI (AIS-A), who could neither contract their leg muscles nor take a single step, were implanted with a new lead developed by ONWARD. On the first day following implant, all participants were able to take steps independently on a treadmill with body weight support. After five months of rehabilitation, they were able to use their legs to stand, walk, swim, and/or cycle, and also regained control of their trunk muscles. The recovery of both leg and trunk motor function enabled participants to stand independently in community settings.

In 2022, the .NeuroRestore team published groundbreaking research on several topics that may be important for ONWARD in the future:

**Therapy to Restore Movement in Hands & Arms**

An article in *Nature Neuroscience*[3] presenting a potentially more effective approach to restore movement and function in the upper limbs after SCI using an implantable neurostimulation system that modulates the spinal cord region involved in controlling hand and arm function. This preclinical data indicated that precise electrical stimulation targeting relevant spinal cord segments enhanced muscle activation and strength and facilitated more efficient hand and arm movements.

**Treating Hypotension for Neurodegenerative Condition**

A study in the *New England Journal of Medicine* (NEJM)[4] presenting the case of a 48 year-old person suffering from MSA-P, a form of Parkinson's disease that affects the sympathetic nervous system. For more than 18 months, severe orthostatic hypotension (low blood pressure) had left this patient bedridden and unable to walk or stand. Following the implant of a system that stimulates the spinal cord, the patient was able to walk more than 250 meters.

This implant technique had already been used to treat orthostatic hypotension in people with SCI, but this was the first time the approach had been shown to improve the quality of life of a person suffering from a neurodegenerative disease.

**Identifying Neurons that Restore Walking after Paralysis**

A study in *Nature*[5] identified the specific neurons that are activated and remodeled by spinal cord stimulation, enabling people with SCI to stand, walk, and rebuild muscle mass. This discovery marks a fundamental, scientific breakthrough. The researchers believe it is crucial to understand exactly how neuronal reorganization occurs in order to develop more effective treatments and improve the lives of as many people as possible.

This paper also detailed the multi-year STIMO study, in which all participants regained motor function and the ability to walk after targeted epidural electrical stimulation of the area of the spinal cord that controls leg movement.

## ARC Therapy: A Breakthrough in Neuromodulation Technology

ONWARD's ARC Therapy applies targeted, programmed stimulation of the spinal cord to restore movement, independence, and health in people with SCI. The stimulation can be delivered by an implantable platform, called ARC$^{IM}$, or an external, transcutaneous platform, called ARC$^{EX}$.

## Spinal Cord Injury Disrupts the Brain-Body Connection

When the spinal cord is injured, communication between the brain and the parts of the nervous system located beneath the lesion is interrupted, either completely or partially. The person may lose all feeling or movement – or both – in these areas. Functions and organs controlled by the autonomic nervous system may also be affected, leading to difficulty with breathing, swallowing, regulating blood pressure, sexual arousal, and bowel and bladder function. This disruption of the body-brain feedback loop can cause a host of debilitating conditions. People with SCI at the thoracic or cervical level are most affected by this loss of function.

Nevertheless, even in cases of complete SCI, some neural pathways in the spinal cord remain intact but inactive. At present, rehabilitation approaches aim to mobilize these latent nerve connections and promote regeneration through intensive physiotherapy. Unfortunately, these activity-based therapies have few benefits for people who cannot produce movements voluntarily. Some symptoms and conditions can be managed with medication, such as antispasmodics to reduce involuntary muscle contractions, or with devices, such as catheters to facilitate urination. However, these solutions can be cumbersome and carry the risk of harmful side effects.

There is an urgent need for more effective therapies that enable people with SCI to live more independent, high-quality lives. This is where ONWARD's ARC Therapy has the potential to make a dramatic impact.

## ARC Therapy Activates Intact Nerve Fibers With Biomimetic Stimulation

As detailed in the previous section, the technology developed by ONWARD is based on pioneering research over the last two decades, led by Prof. Courtine and Dr. Bloch, which has pinpointed the location of neurons in the spinal cord responsible for triggering a movement or function.

By delivering precisely timed and calibrated electrical impulses to specific areas of the spinal cord, ARC Therapy mimics the natural pattern of nerve signals sent by the brain. When combined with voluntary efforts to move, this enables users to improve motor control in the arms, legs, or trunk, making daily activities, like moving in and out of a wheelchair, much easier. Moreover, programmed neurostimulation has the potential to improve the management of internal functions, chiefly blood pressure and bowel and bladder control.

Moreover, programmed neurostimulation has the potential to improve the management of internal functions, chiefly regulation of blood pressure and bowel and bladder control.

Most participants in clinical trials using ARC Therapy regain some degree of independent movement even when the stimulation is switched off. This remarkable result can be explained by the fact that ARC Therapy stimulates intact nerve fibers responsible for carrying messages from the body back to the spinal cord (afferent nerves), and "retrains" them to perform a different function, showing the remarkable plasticity of the nervous system.

## Three Priority Indications to Improve Quality of Life After SCI

### Upper Limb Mobility

Since 2015, 60% of new SCIs in the US have resulted in some form of tetraplegia[6]. Injuries at the cervical level of the spine (C1-C7) can result in loss of sensory and motor connections to all areas below the neck, including the arms and legs. Without the use of our hands, most activities of daily life (such as grooming and eating) become extremely challenging. Better arm and hand function is therefore an important rehabilitation goal for a majority of people with SCI, consistently ranked ahead of walking or sexual function[7].

In 2022, we completed follow-up in our Up-LIFT pivotal and LIFT Home clinical trials. The Up-LIFT study was designed to evaluate the safety and effectiveness of non-invasive electrical spinal cord stimulation administered by a clinical version of ARC$^{EX}$ to treat functional deficits of the upper limbs in people with chronic tetraplegia. Positive topline results from the Up-LIFT study were announced in September 2022, showing that the study had met its primary effectiveness endpoint of improvement in upper extremity strength and function, with no reported serious device-related adverse events.

### Blood Pressure Regulation

The inability to regulate blood pressure following an SCI has profound consequences in both the acute and chronic stages and affects nearly 40% of people with SCI[8]. Immediately after injury, blood rushes to the area of the lesion and causes swelling, which starves the nerve cells of oxygen, compounding the initial damage. The outcome for many patients could be vastly improved if clinicians were able to intervene immediately to prevent inflammation by controlling blood pressure, blood flow, and oxygenation.

At the chronic stage, after the injury has healed, fluctuations in blood pressure drastically impact quality of life, especially for people with tetraplegia. It can cause a range of debilitating conditions, including stroke, fatigue, chronic hypotension, and a life-threatening form of hypertension known as autonomic dysreflexia[9]. Chronic hypotension affects a person's ability to perform everyday movements like sitting up or leaning over and can inhibit their ability to engage in activity-based rehabilitation.

The spinal lead developed by ONWARD specifically for blood pressure regulation has the potential to not only better regulate blood pressure, but also, thanks to its placement in the thoracic area, to improve the tone and control of the trunk muscles.

In 2022, we reported positive interim clinical outcomes from the first ten people treated with implantable ARC Therapy to regulate blood pressure, including HemON study participants. ARC$^{IM}$ Therapy immediately improved blood pressure levels in all study participants, who also reported fewer episodes of hypotension, improved quality of life, increased energy and vitality, and reduced dizziness. Based on these promising interim outcomes[10], we are preparing to initiate further clinical trials, to include U.S. participants, in 2023.

### Lower Limb Mobility

In addition to blood pressure regulation, we plan to further investigate the use of ARC$^{IM}$ to improve mobility by restoring movement in the legs and feet. This will build on the success of STIMO, a first-in-human study that determined the safety and effectiveness of our therapy to restore walking in individuals with chronic SCI resulting in complete or partial paraplegia.

Starting in 2016, nine participants received high-intensity neurorehabilitation that combined precisely timed epidural stimulation with over-ground, robot-assisted rehabilitation training. After completing the STIMO program, all participants reported improvements in mobility and substantial neurological recovery. Several were able to walk on a treadmill without using their hands for support and, more remarkably, to stand and walk at will even while the stimulation was inactive.

While walking may seem like an ambitious goal for many people with SCI, even modest gains in lower limb function can make a big difference. Incorporating ARC$^{IM}$ Therapy in post-acute clinical rehabilitation programs has the potential to vastly improve long-term outcomes for the recently injured by promoting neurological recovery. Additionally, we envision that ARC$^{IM}$ stimulation may someday be used "on the go" to enable a variety of everyday movements, including standing and movement of lower limbs as part of a person's therapy and activities of every day life.

[1]***Wagner***, *F.B., Mignardot, JB., Le Goff-Mignardot, C.G. et al. "Targeted neurotechnology restores walking in humans with spinal cord injury",* ***Nature*** *563, pp. 65–71 (2018)*
[2]*Rowald, A.,* ***Komi****, S.,* ***Demesmaeker****, R., et.al., "Activity-dependent spinal cord neuromodulation rapidly restores trunk and leg motor functions after complete paralysis",* ***Nature Medicine****, vol 28, pp. 260–271 (2022)*
[3]***Barra****, B., Conti, S., Perich, M.G., et.al,, "Epidural electrical stimulation of the cervical dorsal roots restores voluntary upper limb control in paralyzed monkeys",* ***Nature Neuroscience*** *(25), pp. 924–934 (2022)*
[4]***Squair****, J.W., Berney, M., Castro Jimenez, M., et.al., "Implanted System for Orthostatic Hypotension in Multiple-System Atrophy",* ***New England Journal of Medicine****, vol. 386, pp. 1339–1344 (2022)*
[5]***Kathe****, C., Skinnider, M.A., Hutson, T.H., et.al., "The neurons that restore walking after paralysis,"* ***Nature****, vol. 611, pp. 540–547 (2022)*
[6]*National Spinal Cord Injury Statistical Center (NSCISC), Facts and Figures at a Glance, Birmingham, AL: University of Alabama at Birmingham, 2021*
[7]*Source: Candy Tefertiller, PT, DPT, PhD, NCS, Executive Director of Research, Craig Hospital, presented at Unite2Fight Paralysis Conference, 2020. Adapted from Anderson (2004). Targeting Recovery: Priorities of the Spinal Cord-Injured Population. J Neurotrauma. 21(10): 1371-83.*
[8]*Krassioukov A., Claydon V.E. The clinical problems in cardiovascular control following spinal cord injury: an overview. Prog Brain Res. 2006;152:223-9. doi: 10.1016/S0079-6123(05)52014-4. PMID: 16198703*
[9]*Carlozzi, N. E., Fyffe, D., Morin, K. G., Byrne, R., Tulsky, D. S., Victorson, D., Lai, J.-S., & Wecht, J. M. (2013). Impact of blood pressure dysregulation on health-related quality of life in persons with spinal cord injury: Development of a conceptual model. Archives of Physical Medicine and Rehabilitation, 94(9), 1721–1730. https://doi.org/10.1016/j.apmr.2013.02.024*
*Wecht, J. M. (2022). Management of blood pressure disorders in individuals with spinal cord injury. Current Opinion in Pharmacology, 62, 60–63. https://doi.org/10.1016/j.coph.2021.10.003*
[10]*ONWARD press release issued 8 December 2023 - ONWARD Reports Interim Clinical Outcomes for Implantable ARC Therapy Demonstrating Potential to Improve Blood Pressure Regulation after Spinal Cord Injury*

## Two platforms, one system

ONWARD has developed two targeted, programmable neurostimulation platforms: an implantable system, ARC$^{IM}$, and a non-invasive, transcutaneous system, ARC$^{EX}$, both of which have been awarded FDA Breakthrough Device Designation for a range of indications.

Both systems contain the same basic elements: an electrical impulse generator, electrodes placed in proximity to the spinal cord, and a programmer that enables clinicians to set stimulation therapy parameters and users to control therapy.

The two ARC Therapy platforms share common components and have a similar user interface. This optimizes our use of development resources while providing users with a consistent, easy-to-use experience. We envision that ARC$^{IM}$ and ARC$^{EX}$ may be used in conjunction in the same individual, for example leveraging ARC$^{IM}$ for blood pressure regulation while using ARC$^{EX}$ for upper limb training.

# ARC Therapy Product Development

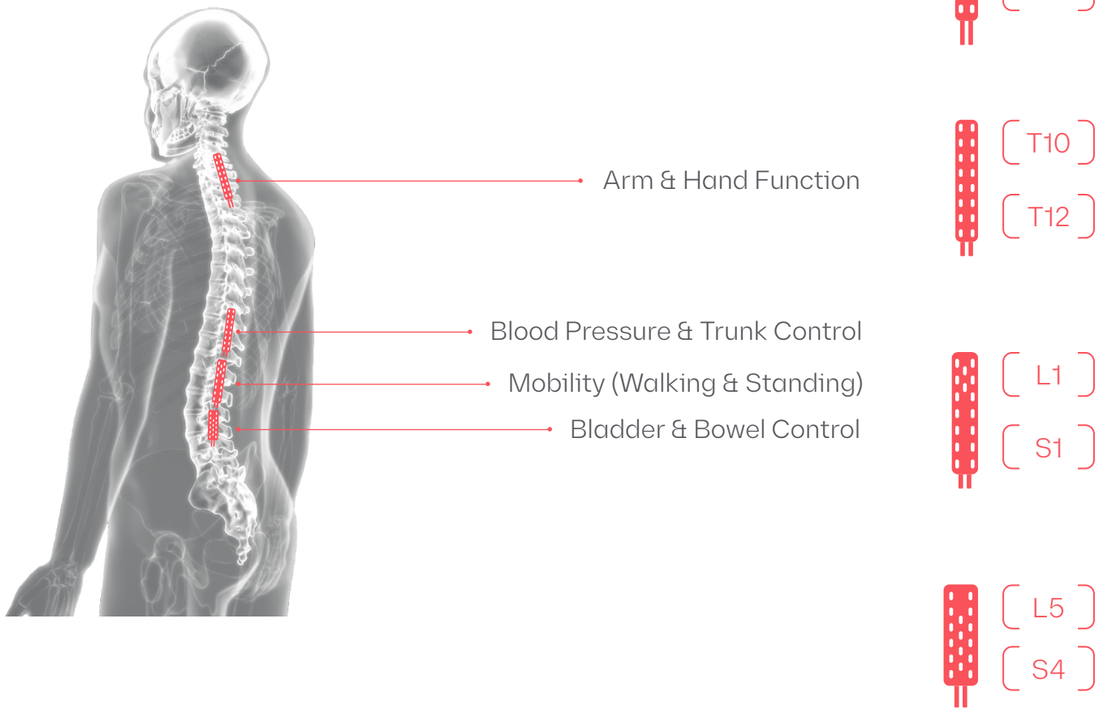
**ARC$^{IM}$** has four components (see next page)[1]:

- A **lead** implanted on the spinal cord in the area corresponding to the movement or function being targeted by the therapy. ONWARD is currently developing a family of leads that are optimized for precise placement in different areas of the spinal cord, both in terms of their shape and the configuration of the electrodes.
- An **implantable pulse generator** (IPG) implanted under the skin in the abdominal area and connected to the lead through a wire. When switched on, this device delivers precisely timed and calibrated bursts of electricity to specific electrodes in the lead.
- An **external hub** that connects wirelessly to the IPG to turn therapy on or off, set or update the frequency and intensity of the impulses, recharge the device through the skin, and integrate external sensors via wireless connections and sensor-specific algorithms. The hub is worn on a belt around the waist.
- **Dedicated apps for efficiency and ease of use: ARC$^{IM}$ PRO app** that clinicians use to create and adjust stimulation programs using a tablet connected wirelessly to the Hub. ONWARD expects to use mobile phone and smartwatch technology to enable users to turn the stimulation on or off and adjust certain parameters through the myARC$^{IM}$ app using voice commands.


[1]*The smartwatch in the graphic may be a smartphone once development has been completed*
*Note: The renderings in the above graphic are illustrative; the design of commercial products may differ.*

## ARC$^{IM}$ Leads

**ARC$^{IM}$** is currently targeted toward improving lower limb mobility and blood pressure regulation. Other potential indications may be explored in the future, including spasticity reduction, improved sexual function, and bladder control, each enabled by further development of the ONWARD proprietary lead portfolio.



ARC EX

**ARC$^{EX}$** is targeted toward improving strength and function of the upper limbs. It is designed for a typical, periodic use in rehabilitation sessions in the clinic and at home. In the future, ARC$^{EX}$ may be used to target additional indications, such as trunk control and mobility.

**ARC$^{EX}$** has three components:

1. **External electrodes** placed on the skin of the neck near the area of the spinal cord that controls movement in the arms and hands.
2. A **stimulator** that delivers programmed electrical impulses directly to the electrodes.
3. **Dedicated apps for efficiency and ease of use: ARC$^{EX}$ PRO app,** which connects wirelessly to the stimulator to program the therapy and adjust parameters and the MyARC$^{EX}$ app for users to easily control the stimulation.

**ARC$^{EX}$ Non-Invasive Platform**

External system for transcutaneous stimulation of the spinal cord


Note: The renderings in the above graphic are illustrative; the design of commercial products may differ.

# Clinical Trials & Regulatory Activity

The development, manufacture, and marketing of ONWARD's ARC Therapy and associated technology is subject to government regulation in the United States, Europe, and other countries. To apply for regulatory clearance or approval to market our devices in any of these jurisdictions, we must complete extensive human clinical trials that demonstrate their safety and efficacy. In the US, clinical trials are a requirement for Premarket Approval (PMA) and increasingly also for de novo clearance and 510(k) submission, all of which we expect to pursue for ARC therapies. Similarly, under the European Medical Device Regulation (MDR), clinical investigations are required in view of completing conformity procedures to obtain a CE mark, a prerequisite for marketing the device in the European Economic Area (EEA).

**FDA Regulatory Process**

To obtain FDA clearance or approval for a medical device, companies must complete several steps:

1. Determine the device's classification (Class I, II or III).

   In the US, ARC$^{IM}$ is a Class III[12] device that will require PMA approval, although for at least one indication it may pursue Humanitarian Device Exemption (HDE) approval. ARC$^{EX}$ is expected to be a Class II device.

2. Develop the prototype and conduct preclinical testing and verification.

3. Conduct human clinical trials (early feasibility studies, followed by feasibility studies and then pivotal studies) and improve the investigational device based on study results.

In the US, clinical trials of investigational devices must be conducted in accordance with the FDA's investigational device exemption (IDE) regulations, which govern labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting, and monitoring responsibilities of study sponsors and investigators.

If the device presents a "significant risk" to human health, as defined by the FDA, the device sponsor must submit an IDE application, supported by appropriate data, such as animal and or laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB) for each clinical site. The IRB is responsible for the initial and continuing review of the IDE and may pose additional requirements for the conduct of the study.

Once the IDE application is approved by the FDA and relevant IRBs, human clinical trials may begin at a specific number of sites and with a specific number of patients.

If the device presents a non-significant risk to human health, the sponsor may begin the clinical trial after obtaining approval of one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements.

ONWARD plans to submit an IDE application for the ARC$^{IM}$ blood pressure and mobility indications. For ARC$^{EX}$ upper limbs indication, ONWARD will follow abbreviated IDE requirements.

During the study, ONWARD, as the study sponsor, is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, and ensuring IRB review and adverse event reporting. The clinical investigators we work with are also subject to FDA regulations and must obtain informed consent from patients, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements.

4. Submit a pre-market notification or application, in the case of a Class II or Class III device, which can be one of the following:

    a. 510(k): a premarketing submission to demonstrate equivalence to existing device(s) to obtain clearance that the device to be marketed is safe and effective.

    b. Premarket Approval (PMA), an application containing sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective for its intended use or uses.

    c. Humanitarian Device Exemption (HDE), an approval pathway created by the FDA for a humanitarian use device (HUD) intended to treat or diagnose a disease or condition that affects fewer than 8,000 individuals in the US per year. The HDE application is similar in both form and content to the PMA application but is exempt from the PMA's effectiveness requirements.

    d. De novo classification, also known as the Evaluation of Automatic Class III Designation. Created under the Food and Drug Administration Modernization Act of 1997 (FDAMA), this option provides an alternate pathway to classify novel devices that carry low to moderate risk. Devices classified through the de novo process may be marketed and used as predicates for future 510(k) submissions.

5. Wait for FDA review and approval. During this process FDA may request several clarifications to be provided by the manufacturer.

6. Maintain FDA compliance for the device's lifespan.

### EU Regulatory Process

To be marketed in member countries of the European Economic Area (EEA), our products must comply with the essential requirements of the new Medical Devices Regulation (MDR) (2017/745), which became fully applicable on 26 May 2021. The regulation aims to ensure that a device is deemed acceptable across several dimensions, including its appropriateness for the intended use, its safety, performance, labeling and packaging, and the effects of transportation and storage, and that it shows a positive balance of benefit versus risk for the end user.

To obtain approval to market a device in the EEA, companies must:

1. Determine the device's classification (Class I, IIa, IIb, or III) according to the associated risks.

    In Europe, ARC$^{IM}$ is expected to be designated as Class III, and ARC$^{EX}$ is expected to be designated as Class IIa.

    In Europe, ARC$^{IM}$ is expected to be designated as Class III, and ARC$^{EX}$ is expected to be designated as Class IIa.

2. Establish a quality system (QMS) to manage the medical device. The QMS is audited annually by the notified body, resulting in the issuance of a certificate that establishes that the QMS is compliant with the ISO 13485 standard.

3. Produce a technical file to satisfy EU MDR General Safety and Performance Requirements (GDPR), including the following information:

- Product description and specifications
- Manufacturing information
- Risk management file
- Design verification and validation test reports
- Clinical evaluation
- Labeling

For Class III devices, a Design Dossier must be compiled containing the data of the technical file along with a description of the design process for the device.

4. Undergo review by a notified body to prove device conformity.

   The conformity assessment procedure varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), this conformity assessment is conducted by a notified body accredited by a member state of the EEA.

   A successful assessment results in the issuance of the CE marking certificate for the medical device along with an ISO 13485 certificate that establishes that the device is compliant with the General Safety and Performance Requirements and European standards.

5. Declare conformity of medical device

   The Declaration of Conformity is a legally binding document issued by the company which declares that the device meets all of the General Safety and Performance Requirements as laid out by EU MDR and any other applicable regulatory standards.

**Clinical Trials**

Clinical trials are an essential part of the regulatory process. Like any other step in the process of developing and testing a new medical device, it is important to note that the results of clinical trials may be unfavorable; moreover, even if the intended safety and efficacy success criteria are achieved, the trial results may not be considered sufficient for regulatory authorities to grant approval or clearance of a product. Additionally, after a trial begins, it may be terminated at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. For more information on ONWARD's clinical trials, please refer to the  section in the operational review.

# Commercialization

ONWARD does not currently offer any products for commercial sale. We are working towards approval of the ARC$^{IM}$ device for the blood pressure indication and aim to receive regulatory clearance and start commercialization in late 2025. We believe that we will receive the necessary regulatory approvals in the US and Europe to start commercializing ARC$^{EX}$ in late 2023. However, our plans to commercialize our products depend on our ability to demonstrate their safety and effectiveness to regulatory authorities, as described in the previous section.

**Geographical Focus & Commercial Objectives**

ONWARD plans to market ARC Therapy products in the US and Europe, where most people with SCI are cared for by a limited number of trauma and rehabilitation centers. When people suffer an SCI, they typically undergo emergency surgery in a trauma center, after which they spend one week in intensive care. They then begin rehabilitation training, which is generally provided by specialized clinics that have the necessary expertise and equipment.

In most cases, this rehabilitation lasts three to six months, although in some markets it can extend to one year, after which ongoing therapy aims chiefly to maintain functional gains. They may also seek rehabilitation in later years, due to complications, or as new therapies emerge that may result in restoration of function.

In the initial period following commercial launch, our focus will be on the US and four select European markets: Germany, France, the UK and the Netherlands. These markets were selected based on their attractive reimbursement environment for new medical technologies and their sophisticated SCI rehabilitation infrastructure. The Company may modify target markets to optimize likelihood of commercial success.

We plan to deploy a direct sales and service organization, as the total number of facilities to be targeted — whether to market our therapies or to support surgical interventions — around 200. If FDA clearance or approval or CE certification permits us to pursue entry into other large markets, including in Asia, we will likely do so via a distribution partner.

We will continue to evolve our commercial strategy to optimize the Company's probability of success.

# Commercial Strategy

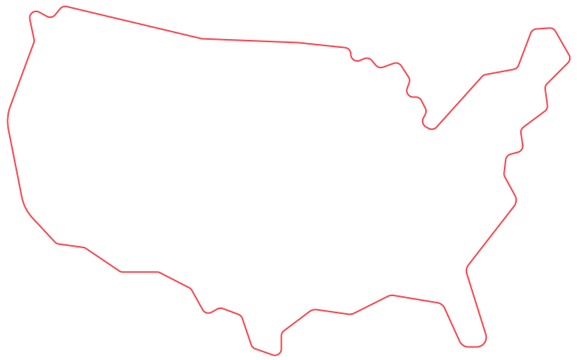
## Pursue highly concentrated customer base with direct field organization

**Call Points**

~200

(2019)

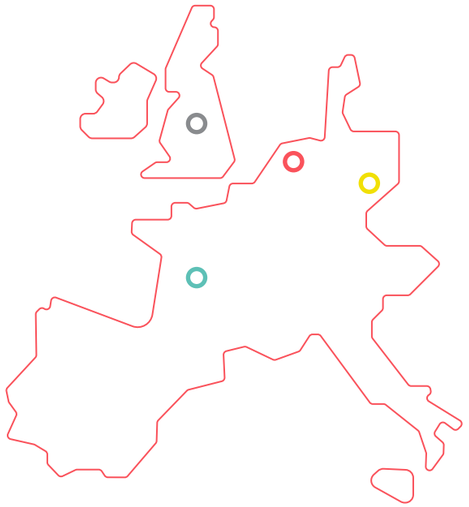
**US**



105

Specialized Rehabilitation Clinics

**Europe**



- France (FR)
- Germany (DE)
- Netherlands (NL)
- United Kingdom (UK)

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Specialized Rehabilitation Clinics

**Focus**

Target the US and select European markets with sophisticated neurorehabilitation infrastructure and favorable reimbursement for innovative medical technology

## Specific customer targets at each stage in patient journey

# Clinician Customers in Patient Journey

**Acute Phase**

**Injury**

**Sub-Acute Phase**

**Decompression Surgery**
24 hours

**Intensive Care**
~7 days

**Intermediate Phase**

**Rehabilitation**
3-6 months

**Chronic Phase**

**Plateau**
12+ months

### Trauma Centers

Trauma and functional neurosurgeons

### SCI Rehabilitation Clinics

Neurologists, rehabilitation physicians and therapists

Functional neurosurgeons

Patients & caregivers

# Referral Pathway

## Physicians will prescribe ARC$^{EX}$ for clinic or home use and refer patients for ARC$^{IM}$ implants

**Decision-Maker**

**Neurologists & Rehabilitation Clinicians**

ARC EX

- Order clinic use
- Prescribe home use

ARC IM


Referral to functional neurosurgeon for implant surgery (likely <2hr)

### Rehabilitation Clinics

Our marketing efforts will focus on clinicians managing SCI patients in specialty rehabilitation clinics. These include neurologists, rehabilitation physicians, physical therapists, and occupational therapists who provide post-injury rehabilitation training and ongoing support to those who are chronically injured. The latter constitutes the largest pool of SCI patients globally.

We expect clinicians to use our therapies as follows:

- Apply ARC Therapy using ARC$^{EX}$ in clinics
- Prescribe ARC$^{EX}$ for use at home
- Refer patients to functional neurosurgeons for implantation of ARC$^{IM}$ and subsequent use of ARC Therapy in clinics and at home

There are a limited number of specialty rehabilitation clinics in the US and Europe. In the US, we expect to target the 105 SCI rehabilitation clinics certified by the Commission of Accredited Rehabilitation Facilities (CARF). CARF certification means that a clinic has a comprehensive integrated inpatient rehabilitation program, outpatient medical rehabilitation program, home and community services, residential rehabilitation, and vocational services[1]. Though SCI rehabilitation in the US is not limited to these centers, CARF-certified clinics provide a robust referral base for the Company's products and will serve as focused and fertile marketing targets.

In the four selected European markets, there are a total of 83 SCI specialty rehabilitation centers: 27 in Germany[2], 10 in the UK[3], 8 in the Netherlands[4], and 38 in France.

### Hospitals & Ambulatory Surgery Centers

When patients are referred for an implant of ARC$^{IM}$, surgery is typically carried out in hospitals or ambulatory surgery centers by functional neurosurgeons. These neurosurgeons are already familiar with device therapy and neuromodulation, and routinely perform implants for deep brain stimulation and spinal cord stimulation for pain therapy. As the implant procedure for ARC$^{IM}$ is substantially similar to that for spinal cord stimulation for pain, we expect little resistance to adoption and a minimal training burden.

### Trauma Centers

In addition to rehabilitation centers, we plan to target trauma centers to provide our therapies at the acute or subacute stage. Level 1 trauma centers provide total care for all aspects of an injury, and prompt availability of relevant specialists such as neurosurgeons[5]. They are thus an access point to acute and subacute SCI patients, and to neurosurgeons who can implant ARC$^{IM}$ devices. We envision that the blood pressure management indication may be well suited for acute management of SCI, by helping to stabilize blood pressure and promote spinal cord perfusion.

In the U.S., most SCI patients are treated at just 190 Level 1 or major trauma centers[6]. In the four selected European markets, there are 152 major trauma centers: 27 in the UK[7], 11 in the Netherlands[8], 91 in Germany[9], and 23 in France[10].

**Reimbursement Landscape in the United States**

Upon FDA approval of ARC Therapy in the United States (US), we expect ARC$^{IM}$ will be sold to hospitals and ambulatory surgery centers for use by functional neurosurgeons. We expect ARC$^{EX}$ will be sold to specialty rehabilitation clinics as well as directly to SCI patients for use in the home.

In both US and non-US markets, the Company's ability to successfully commercialize and achieve market acceptance of its products depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including governmental payors, managed care organizations, and private health insurers. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments and increasingly they examine cost effectiveness of medical devices as well as safety and efficacy when making coverage and payment decisions.

Given that no uniform policy for coverage and reimbursement exists across our target markets or even within some markets and coverage and reimbursement can differ significantly from payor to payor, commercialization efforts to identify optimized pathways for reimbursement, coverage, and payment started in 2022 and will continue into 2023. Our clinical and economic evidence generation plans will also continue into 2023 to support third-party payor review.

**MCIT Repeal & TCET Pathway**

In November of 2021, the Centers for Medicare and Medicare Services (CMS) rescinded the Medicare Coverage of Innovative Technology (MCIT) final rule. This rule was originally proposed in September of 2020 with the intent of ensuring Medicare coverage upon FDA clearance for devices which were awarded FDA Breakthrough Designation. Concerns regarding lack of controls to ensure Medicare populations were studied and lack of a mechanism to remove coverage if safety concerns arise were cited as reasons for repeal.

Despite the repeal, CMS reiterated its commitment to create a pathway for coverage upon FDA clearance for Breakthrough Devices and is working with industry stakeholders, physician societies, and patient groups to develop an alternate pathway called Transitional Coverage for Emerging Technologies (TCET). While this pathway is still under consideration, it could positively affect devices with Breakthrough Designations, such as ARC$^{EX}$ and ARC$^{IM}$, by providing Medicare coverage from day one through a post-FDA clearance period.

A public hearing on the matter is scheduled for April 2023.

**Coding & Payment**

Because the implant procedure for ARC$^{IM}$ is substantially similar to that which is currently used to implant spinal cord stimulation devices for pain management, existing codes may be used.

Facility payments include the cost of the device but not physician services, which are billed separately. Medicare pays the Hospital Outpatient Department a single amount for the full system implant, while the Ambulatory Surgery Center is paid separately for the lead and generator implantation, resulting in a higher payment amount. Private payers tend to pay 25% more than Medicare. Medicare payment systems tend to lag new technology. The systems are prospective, such that payment amounts for a given procedure are determined in advance based on historical claims data. The established payments are then applied to a combination of diagnosis and procedure codes. Because they use predetermined fixed-payment amounts, the systems can underpay for new, more impactful technologies. As a result, Medicare created a new-technology payment process for the hospital outpatient setting.

For the hospital outpatient setting, the process for recognizing and rewarding an impactful new technology is called a Transitional-Pass-Through ("TPT") payment. To qualify, a technology must be too new to be represented in Medicare's historical claims data. It must also be clinically significant based on the literature and "not insignificantly" more expensive. TPT status is granted quarterly and can be applied for prior to FDA approval. Acceptance to the program results in two to three years of market-price data gathering before a payment amount is established. Having an FDA-designated breakthrough product satisfies the "clinically significant" criterion. The Company plans to evaluate the pursuit of a TPT payment for its therapies once the first pivotal trial for ARC$^{IM}$ is initiated in the US.

In the inpatient setting, Medicare's New Technology Add-on Payment ("NTAP") provides additional payment for implantable devices for a limited duration, typically up to 3 years. Similar to the outpatient TPT payment process described in the preceding paragraph, the FDA Breakthrough Device Designation awarded to ARC$^{IM}$ increases the likelihood of qualification for NTAP.

There are also existing provider payment codes for physical therapy, which could encompass the use of ARC Therapy. Use of these codes may decrease the evidence requirements for US commercial launch and shorten time to revenue.

ARC$^{EX}$ is designed as Durable Medical Equipment ("DME") and would be categorized under a different set of codes called HCPCS. The initially applicable DME code is a miscellaneous code, which may be used upon FDA clearance and launch of the product. Because this code is intended to be used for new technology it has no set price, allowing the Company to establish its desired price in the marketplace before receiving a product-specific code.

Prior to achieving a specific DME code for ARC$^{EX}$ in the US, the Company can pursue sales through the Veterans Health Administration, through private payors using miscellaneous HCPCS codes, and via direct-to-patient sales. The Company views these as important pathways not only to generate revenue, but to establish pricing history and generate real-world evidence.

**Reimbursement in Europe**

The path forward in Europe is more varied than in the United States. The Company has analyzed the reimbursement environment in four European markets and its launch strategy will consider the attractiveness of their reimbursement posture toward new medical technologies and the sophistication of their SCI rehabilitation infrastructure. Based on these criteria and preliminary inputs that will be further validated in 2023, our most likely initial European market for ARC$^{EX}$ is Germany, with our three other markets (France, the United Kingdom, and the Netherlands) to be included in our current ARC$^{EX}$ market access planning. All four markets are also viable ARC$^{IM}$ targets, with plans to further undertake reimbursement planning in 2023 and 2024.

In Germany, medical devices in the outpatient and physician clinic setting require a new Einheitlicher Bewertungsmaßstab ("EBM") code. Devices used in the home-use setting are governed by the Hilfsmittelverzeichnis ("HMV"), a positive coverage list for home-use medical equipment. HMV categories tend to be highly specific to indication; as a result, ARC$^{EX}$ will likely need a new HMV category. To achieve a new product category, a positive evaluation by Gemeinsamer Bundesausschuss ("G-BA") will be necessary. Once contained within the HMV, reimbursement will be negotiated through individual contracts with statutory health insurances ("SHI"). Our preliminary analysis suggests the timeline for ARC$^{EX}$ reimbursement would be two to four years from CE marking.

For implantable devices, Germany operates a DRG-based system to compensate hospital inpatient admissions. Among the selected markets, Germany may offer the most accessible pathway for inpatient add-on payment. The "NUB" innovation payment (Neue Untersuchungs- und Behandlungsmethoden) affords locally negotiated payment for up to four years. Following the NUB, a permanent DRG assignment or permanent add-on payment in the form of (Zusatzentgelt, ZE) for high-cost services, may be provided.

A new Operationen- und Prozedurenschlüssel ("OPS") code would be required to establish NUB funding or NUB payment. NUB funding would temporarily supplement DRG payment until it could be incorporated into the DRG system. Two neurostimulators have achieved NUB approval in the last three years. NUB funding in Germany could be achieved for ARC$^{IM}$ within as few as 11 months from CE marking.

*[1]CARF International, provider search, United States (carf.org).*
*[2]Deutsche Behandlungszentren (dmgp.de).*
*[3]Medical Management Advice: Royal National Orthopaedic Hospital (rnoh.nhs.uk).*
*[4]PHM50279 93..95 (insci.network).*
*[5]American Trauma Society https://www.amtrauma.org/page/TraumaLevels, retrieved 09AUG2021.*
*[6]MacKenzie E.J., Hoyt D.B., Sacra J.C., et al. National Inventory of Hospital Trauma Centers. JAMA. 2003;289(12):1515–1522. doi:10.1001/jama.289.12.1515.*
*[7]Orthopedic Trauma Association Development of trauma systems in Europe—reports from England: OTA International (lww.com) Retrieved 09 August 2021.*
*[8]National Health Services A4_map (www.nhs.uk) Retrieved 09AUG2021.*
*[9]PHM50279 93..95 (insci.network).*
*[10]France does not have official criteria for trauma center levels as the above countries do; however, Traumabase lists 23 top trauma hospitals in France. Traumabase Registry* ***https://www.traumabase.eu/en_US.***

# People & Culture

We strive to create a positive culture inspired by our ONWARD Code and our compelling vision. We also foster a culture of continuous learning, feedback, and development, providing the necessary tools and opportunities for our people to enhance their skills and grow in their abilities and careers.

Our technology is highly innovative, and we seek talented people who bring boldness and creativity to our organization. We are a diverse team, with 20 nationalities currently represented.

We differentiate ourselves as an employer of choice by fostering a purpose-driven culture with an entrepreneurial mindset. We offer competitive rewards, encourage learning and development, and build leadership and change-management expertise among our current and future leaders.

We have an employee-driven Culture Club that nurtures and reinforces our cultural norms, builds teamwork and common understanding, and supports SCI-focused charitable events sponsored organizations such as Wings for Life and the Christopher & Dana Reeve Foundation.

# The ONWARD Code

## We are OPEN
We seek great ideas from any source. We are hungry for feedback.
We accept criticism with humility.

## We are TRUSTING
We assume positive intent. We count on each other to deliver.
We speak truth to our leaders and teammates.

## We are COLLABORATIVE
We are a team. We find ways to work well together.
We value our external partnerships.

## We are PASSIONATE
We admire the courage of those we serve.
We are driven to fulfill our Vision. We will not fail.

## We are EMPOWERED
We encourage ideas. We allow mistakes.
Everyone is accountable.

## We are COMMITTED
We pursue a noble cause. We are never distracted nor deterred. We are grateful for the responsibility we shoulder.

## We are PRAGMATIC
We find a way. We surmount obstacles. We find fulfillment in overcoming.

## We are INNOVATIVE
We dream big. Limits do not contain us.
Our imagination defines the possible.

Our Code is communicated as part of employee onboarding and reconfirmed in our monthly meetups. The Company believes it is important to cultivate an open and transparent culture that allows employees to express, in good faith, any concern they may have. Our employees are encouraged to raise concerns without fear of retaliation, knowing that concerns will be treated confidentially, seriously, fairly and promptly. During the financial year 2022, no concerns were reported.

### A Great Place to Work

We strive to provide a positive employee experience, starting with the hiring process. We have implemented improvements in our onboarding process to ensure a smooth and positive experience for our new team members, with the support of their manager and a buddy. We have a talent-management system to help drive a culture of performance, accountability, and development. We use this system to track individual objectives, give feedback to colleagues, and capture employee development and performance.

We frequently host speakers from the SCI community who help us stay connected to our vision and to the meaning and urgency of our work. We participate in charitable events, often supporting causes to help people with SCI.

### Competitive Hiring

Software engineers and other technology-focused professionals account for about 65% of our recent new hires. As demand for technology talent outstrips supply, attracting the right people in this highly competitive landscape becomes essential. We endeavor to attract the best candidates: people who are motivated by our vision and the opportunity to work on true breakthroughs, rather than incremental gains.

By establishing in-house recruitment capacity, leveraging our professional networks, and building partnerships with key academic institutions and other relevant organizations, we have been able to attract great talent. Our employee referral program also incentivizes our employees to leverage the power of their networks to recruit people who are a good cultural and organizational fit.

We offer competitive compensation and benefits packages, key for attracting and retaining talent. Long-term incentives are offered to our senior management and key individuals as part of our remuneration philosophy. We encourage share ownership among all of our employees through a stock option plan. This aligns our long-term incentives with our long-term objectives, as grants are conditional on continued employment until the time of vesting.

### Employee Well-Being

The well-being of our employees is important to us. Hence, we continued to offer workshops and other activities centered on mental health and well-being. In addition, we adjusted to the current trend of offering our employees more flexible, hybrid ways of working where possible, unless their work requires access to specialized equipment and facilities, thereby necessitating regular presence in the office.

# Corporate Responsibility

ONWARD is committed to being a responsible organization that creates long-term value for all our stakeholders. Environmental, social, and governance (ESG) principles are integral to the way we do business. They are captured in our ONWARD Code, our Articles of Association (AOA), our Code of Conduct (COC), our culture, business practices, operations and supplier agreements.

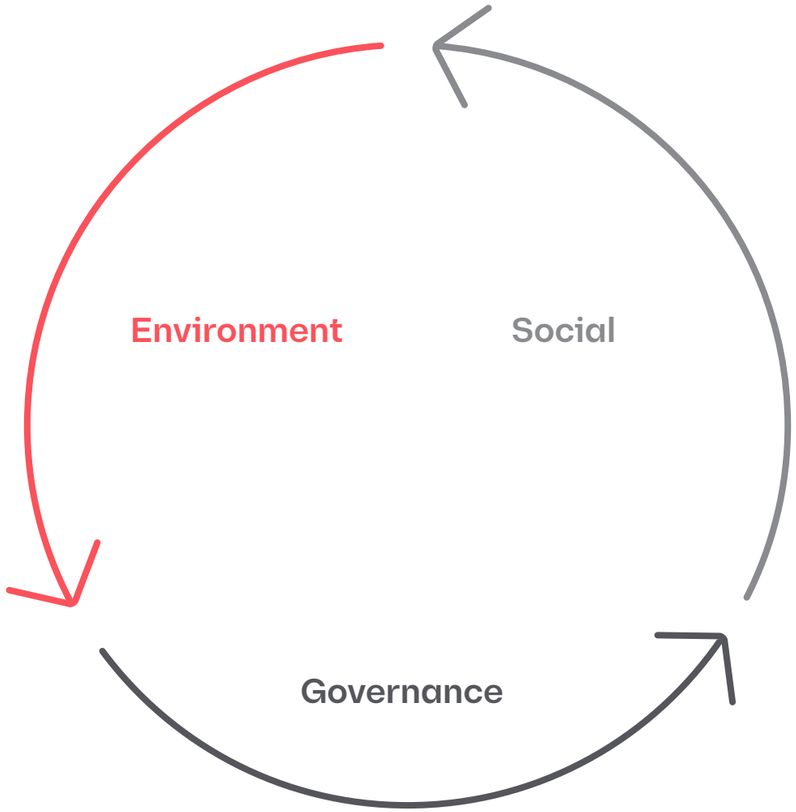
**ESG Principles**

Our ESG strategy rests on five core principles:

- **Innovating for the underserved:** There is no cure for SCI. Our therapies are among the first to offer the potential to help people with spinal cord injury regain movement and other functions, improving quality of life for a large, underserved group of people. Our products also have potential to benefit large populations of stroke sufferers and people with Parkinson's disease. Underscoring the innovative nature of our work, we have been granted eight Breakthrough Device Designations (BDD) by the US FDA and have over 330 issued or pending patents worldwide. We continuously innovate and strive to get such designations for other indications to be able to make a difference in the lives of even more people.
- **Partnering with patient groups:** We enjoy excellent relationships with the world's leading patient advocacy groups for people with spinal cord injury. The Christopher and Dana Reeve Foundation, the world's largest such organization, is an investor in ONWARD. We also collaborate with Wings for Life in Europe, the Praxis Foundation in Canada and International Spinal Research Trust in the UK. Our collaboration with these groups helps us innovate in ways that make the greatest difference for people with spinal cord injury.
- **Attracting and retaining the best talent:** To deliver on our vision, we are committed to creating an unrivaled and inclusive environment for our employees. We care deeply about the well-being and continuous development of our staff as evidenced by the various programs we have put in place, such as our well-being program. Having a highly motivated and engaged workforce enables us to retain and attract top talent. We also engage with partners with spinal cord injury as consultants, who enable our workforce to have a better understanding of the challenges that they face. ONWARD recognizes and welcomes the value of diversity with respect to age, gender, race, ethnicity, nationality, sexual orientation and other important cultural differences.
- **Minimizing our environmental footprint:** In our operations, we strive to reduce our carbon footprint, for instance by replacing air travel with videoconferencing except for the most pressing business needs and by encouraging a hybrid workplace, thus reducing our employees' commute. Additionally, we work with our suppliers to minimize waste in the manufacturing process, consume electricity generated almost exclusively from renewable sources and implement recycling programs in our offices.
- **Maintaining high ethical standards:** At ONWARD, we are open and act with integrity. We are committed to high ethical standards in dealing with our business partners as outlined in our Code of Conduct, which covers anti-bribery and anti-money laundering, government relations and political affairs and international business practices. Our Code of Conduct ensures our people across the organization understand what is expected of them when acting on behalf of the Company. We aim to comply with all applicable anti-bribery laws, including the US Foreign Corrupt Practices Act. We apply the highest quality and safety standards to everything that we do, and we ensure strong labor practices in our supply chain. We also work hard to secure key personal data and comply with GDPR (General Data Protection Regulations) and HIPAA. We uphold human rights and operate in geographies with a strong track record on this topic.

# ESG Strategy

## Our ESG Strategy includes five principles in support of nine UN Sustainable Development Goals[1]




### Environment

**Minimizing our environmental footprint**
We strive to reduce our carbon footprint and waste in our operations

### Social

**Innovating for the underserved**
We innovate to help people with Spinal Cord Injury, empowered by movement, to enjoy life in every way that matters to them

**Partnering with patient groups**
We enjoy excellent relationships with the world's leading patient-advocacy groups for people with SCI

### Governance

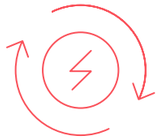
**Maintaining high ethical standards**
We act with integrity, respect human rights and apply the highest quality and safety standards

**Attracting & retaining top talent**
We are committed to creating a positive, diverse and inclusive work environment for all our employees, enhanced by continuous development

*Source: 1* ***https://sdgs.un.org/goals***

# ESG Summary

## Environment



99%

Share of electricity consumed generated from renewable sources[1]

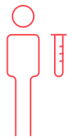
## Social

€13.1M

R&D investment (2022 R&D expenses)

€5.7M

Spend on research and clinical trials in 2022



8

Clinical trials sponsored or supported in 2022

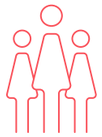
—

9

Indications under clinical or pre-clinical evaluation

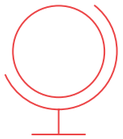
[1]*Weighted average of Lausanne and Eindhoven offices based on data provided by Services industriels de Lausanne (2021 data) and High Tech Campus Eindhoven*

# Governance



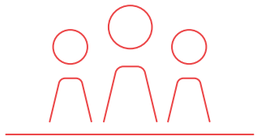
50%

Share of leadership roles[1] held by women



41%

Share of supervisor and manager roles[2] held by women globally



33%

Share of Board Director and Interim Director seats held by women

[1]*Defined as full-time roles within the Company's Leadership Team (based on team composition as of 01 February 2023)*
[2]*Supervisor or manager role defined as managing one or more reports*

# Privacy & Data Governance

ONWARD is committed to ensuring that data security and confidentiality are built into our products and processes. The personal data we process in the course of our operations — including health and medical information — cover our suppliers and business contacts, applicants, visitors and website visitors, our employees, and our customers. We collect patient health data with the sole purpose of continually improving the efficiency and safety of our therapies.

We are subject to various regional, national, and state laws that protect the confidentiality and security of patient health information, including patient medical records. We are committed to applying the two most rigorous privacy regulations to our global operations, namely the United States' Health Insurance Portability and Accountability Act (HIPAA) and the European Union's General Data Protection Regulation ((EU) 2016/679; GDPR). This legislation includes the right to access or amend certain records containing protected health information or to request that its use or disclosure be restricted.

To that end, we have appointed an external Data Protection Officer. This service is provided by DPO Consulting, which has extensive experience in Data Protection regulations. We have established a Data Privacy Committee and a Data Protection Policy.

We have also strengthened our products' compliance with cybersecurity and data protection requirements under GDPR and HIPAA. We have started to create traceability in accordance with relevant standards and built evidence that our products are compliant with the regulations. We have evaluated our process for compliance with GDPR and HIPAA requirements, specifically as we prepare for commercialization, and are working to close any gaps in 2023. We are hardening our data management processes, and we regularly train our staff on security and privacy issues.

# Operational Review

ONWARD made considerable progress in 2022:

**Science & Intellectual Property**

As the pioneer in our space, we have forged relationships and exclusively licensed important intellectual property from many of the world's leading neuroscience research laboratories, such as Caltech (USA), University of California at Los Angeles (USA), University of Louisville (USA), and University of British Columbia (Canada).

Our primary research partnership is with .NeuroRestore, a joint research initiative of EPFL and CHUV in Lausanne, Switzerland, with whom we have an exclusive IP licensing agreement. In 2021, we signed a framework agreement with .NeuroRestore governing future research initiatives, as well as contracts covering existing and ongoing research. In addition, we supported .NeuroRestore's research on blood pressure, mobility, and incontinence.

Benefitting from these research collaborations, and combined with our own innovations, the Company's IP portfolio grew to more than 330 issued or pending patents in 2022. We plan to continue to consolidate and grow our IP portfolio in 2023 and beyond — a key ONWARD strength.

**Research & Development**

Our engineering team made advancements across several development initiatives in 2022:

- ARC$^{EX}$ System development: Considerable progress was made on all aspects of the system. Multiple rounds of user-centric formative studies were completed, including software and hardware UI/UX on release candidate systems and incorporation of learnings from the Up-LIFT study. Design inputs then were locked and development of the most recent generation of the system is now nearing completion. Work has begun on transferring the design to manufacturing, procuring production materials, and initiating supply-chain activities.
- ARC$^{IM}$ Lead development: The ARC$^{IM}$ thoracic lead development, design verification, and validation have all been completed. The lead is now ready for submission to regulatory bodies and will be part of near-term submissions in support of current study updates as well as new feasibility and pivotal trials. The ARC$^{IM}$ Lumbar Lead models are also nearing development completion, with prototyping and designs finalized. A minimal set of design-verification testing remains, since the majority of tests can be leveraged from those done for the Thoracic model.
- Agile at Scale: An integration-focused, cross department, development approach that leverages agile ceremonies and user centric design principals, was rolled out across the development organization in 2022. Agile at Scale better enables cross-team collaboration, feature realization, rapid feedback cycles with stakeholders and customers, and the organization's ability to support multiple, simultaneous product development initiatives. Further improvements are expected as the implementation, infrastructure, and methods mature and improve over the course of 2023.

- ARC$^{IM}$ Platform: Following the implant of multiple ARC$^{IM}$ Implantable Pulse Generators (IPGs), several updates were made to the platform to improve features and device performance and to incorporate learnings from proof-of-concept studies and field use. We also continued to support and complete deliverables for the Defense Advanced Research Projects Agency (DARPA) project Phase 2, as described below.

ONWARD is part of a research consortium of partners in the US, Canada, and Switzerland that has been awarded research funding by DARPA to advance innovative SCI therapies. In response to the DARPA Bridging the Gap Plus funding call, the consortium proposed developing a new clinical intervention to modulate blood pressure and spinal cord perfusion and oxygenation in the hours following SCI. The intervention includes spinal cord stimulation using ARC$^{IM}$, combined with implanted sensors for blood pressure and spinal cord perfusion, as well as stem cells and scaffolds to be implanted in the lesion site to promote neural regrowth across the injury.

The DARPA grant is a five-year project (October 2021 to September 2025) for a total of USD 36M, of which ONWARD could potentially receive up to USD 6.3M.

To receive this funding in full, we must meet specific milestones at each stage:

- **Phase 1:** System design, IPG software and firmware update for spinal cord stimulation for blood pressure control (already granted and funding received)
- **Phase 2:** System development completion (already granted and receipt of funding ongoing), development of a dedicated lead (contingent), and clinical evaluation in 10 chronic patients in Switzerland and Canada (contingent)
- **Phase 3:** US Food and Drug Administration (FDA) Investigational Device Exemption secured and clinical proof of concept demonstrated in at least one acute patient (to be granted)

We believe that our involvement in the DARPA consortium will contribute to our leadership and expertise in blood pressure management. We also expect that it will pave the way for the introduction of next-generation systems that may follow the initial configuration of ARC$^{IM}$ that we expect to launch for SCI.

### Clinical & Regulatory

ONWARD's clinical and regulatory team had a productive 2022, filling the indication pipeline and advancing the core ARC$^{EX}$ and ARC$^{IM}$ therapies forward toward market approval for the SCI population. With completion of the Up-LIFT study as well as initiation of work necessary for the ARC$^{IM}$ pivotal study, the team is poised to deliver on several major clinical and regulatory initiatives in 2023.

### Clinical Trials of ARC$^{EX}$ Therapy

In 2022, ONWARD completed the Up-LIFT study, the first large-scale pivotal trial of non-invasive spinal cord stimulation technology. It enrolled 65 subjects at 14 leading SCI research sites throughout the United States, Canada, the United Kingdom, and the Netherlands. The Up-LIFT study is a prospective, single-arm study designed to evaluate the safety and effectiveness of non-invasive electrical spinal cord stimulation to treat upper extremity functional deficits in people with chronic tetraplegia.

Positive topline results from the Up-LIFT study were announced on 13 September 2022, showing that the study had met its primary effectiveness endpoint with no reported serious device-related adverse events, as adjudicated by an independent Data Safety Monitoring Board (DSMB). Detailed results will be made available following review by FDA.

In October 2022, ONWARD announced the successful completion of the LIFT Home study, designed to assess the safety and performance of ARC$^{EX}$ Therapy when used in a home setting. The study enrolled 17 subjects at five leading centers in the US who continued treatment at home subsequent to the Up-LIFT study. Observational data demonstrated that the use of ARC$^{EX}$ System at home resulted in no reported serious adverse events. Participants performed training on activities of daily living three times per week over a one-month period with approximately 97% of these treatment sessions completed, without usability issues, supporting the feasibility of home-based therapy.

### Clinical Trials of ARC$^{IM}$ Therapy

A major company milestone was achieved in May 2022 with the first enrollment in the HemON study designed to evaluate the safety and preliminary efficacy of ARC$^{IM}$ Therapy to improve blood pressure management in people with SCI who suffer from orthostatic hypotension. Orthostatic hypotension is characterized by debilitatingly low blood pressure that may occur when people sit upright, stand, or change body position. Importantly, this marked the first-in-human use of the Company's ARC$^{IM}$ implantable pulse generator (IPG).

In December 2022, ONWARD reported interim clinical outcomes from the first 10 participants treated to regulate blood pressure with ARC Therapy. In addition to a sustained increase in blood pressure levels, participants who were taking an anti-hypotension drug prior to entering the study were able to significantly reduce or discontinue their medication. Participants also reported improved general well-being, including reduced dizziness and improved energy, and those prone to fainting or light-headedness prior to implant indicated that such incidents declined dramatically following treatment with ARC Therapy.

The company has had a highly productive year preparing for several key submissions with the FDA and EU-MDR in 2023 and beyond. Leading into this, in 2022, the Company was granted Breakthrough Device Designation (BDD) by the FDA for three additional indications: (1) for ARC$^{EX}$ for improving or restoring lower extremity sensory and motor function in people with chronic neurological deficits resulting from SCI; and (2) and (3) for treating neurogenic bladder dysfunction in people with SCI for both ARC$^{IM}$ and ARC$^{EX}$. In early 2023, we were granted two additional Breakthrough Device Designation for ARC$^{EX}$ for the alleviation of spasticity and blood pressure regulation. The Company now has a total of eight BDDs for ARC Therapy.  BDD is an FDA program designed to help patients and their physicians receive timely access to technologies that have the potential to provide more effective treatment or diagnosis for debilitating conditions of great unmet need, such as SCI. As part of this designation, the FDA will provide ONWARD with priority review and the opportunity to interact with FDA experts throughout the premarket review phase as the technology moves toward commercialization. The Company currently holds a total of eight Breakthrough Device Designations for ARC Therapy.

### Quality

ONWARD has a global quality system for teams based in the US, the Netherlands, and Switzerland that complies with applicable regulations and standards related to the medical devices industry (MDR and QSR, respectively, for EU and USA). In 2018, we obtained the ISO 13485 certification for design and development. In 2022, the certification scope was expanded to include clinical applications targeted by ARC$^{EX}$ Therapy and new activities to support the upcoming manufacturing and distribution of ARC$^{EX}$ devices.

The most recent audit was conducted and passed in late 2022 by TÜV SÜD, a respected notified body with global reach for neuromodulation devices.

A Quality Plan was established to support the growth of the organization in the coming years and to ensure the operational excellence of the teams and delivery of safe and effective therapy.

We have continued to strengthen our Quality function by hiring additional qualified staff bringing competencies in medical software, suppliers' quality management, design control, and risk management.

## Commercial Operations

ONWARD does not currently offer any products for commercial sale. However, following the expected successful submission of the results of the Up-LIFT trial to regulatory authorities and regulatory clearance, we plan to commercialize ARC$^{EX}$ in the US and Europe in late 2023 to help improve strength and function of the upper extremities.

In late 2025, assuming positive clinical results and related market approvals, we aim to launch ARC$^{IM}$ commercially in the US and select European markets to restore normal blood pressure. In late 2025, we also expect to commercialize ARC$^{IM}$ in the US for mobility via Humanitarian Device Exemption (HDE) from the FDA. (The European authorization process for ARC$^{IM}$ for the mobility indication is not yet determined.)

Given the small number of centers and clinicians responsible for providing rehabilitation training, managing SCI patients, and performing accompanying surgeries (as detailed on p. 72), we plan to deploy our own direct sales and service organization in both the US and Europe, using distribution partners selectively where appropriate.

## Financing

To support operational goals, we will continue to invest in our our R&D activities, conduct clinical trials, and prepare for commercialization. We have successfully raised more than EUR 150M since the Company's founding, with EUR 62M net cash (please refer to Non-IFRS financial measure included in Other Information for the definition of net cash) on the balance sheet at the end of 2022.

We expect our current cash to propel operations through the end of 2024 and will continue to consider opportunities in 2023 to further strengthen our cash position.

[1] *ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes.).*

# Financial Review

This financial review should be read with the operational review and the Company's consolidated financial statements in this Annual Report, which have been prepared in accordance with International Financial Reporting Standards (IFRS) as published by the International Accounting Standards Board and as adopted by the European Union and with Part 9 of Book 2 of the Dutch Civil Code.

| EUR' Million | 2022 | 2021 |
|---|---|---|
| **Total Revenues & Other Income** | **2.1** | **1.4** |
| **Total Operating Expenses** | **(34.2)** | **(30.0)** |
| Research & Development Expenses | (13.1) | (10.6) |
| Clinical & Regulatory expenses | (5.7) | (4.8) |
| Marketing & Market Access Expenses | (2.0) | (1.5) |
| Patent Fees & Related Expenses | (1.5) | (1.4) |
| Quality Assurance Expenses | (1.2) | (1.0) |
| General & Administrative Expenses | (10.6) | (10.7) |
| **Operating Loss for the Period** | **(32.0)** | **(28.6)** |
| Net Finance expense | (1.5) | (5.7) |
| Income Tax expense | 0.8 | (0.0) |
| **Net loss for the period** | **(32.8)** | **(34.3)** |

| At<br>EUR' Million | 31 December<br>2022 | 31 December<br>2021 |
|---|---|---|
| **Net cash position at the end of the period** | **61.8** | **89.4** |
| **Interest-bearing loans** | **(12.7)** | **(11.5)** |
| **Equity** | **52.6** | **82.7** |

### Total Revenues & Other Income

Other income, mainly grant income, increased to EUR 2.1M (2021: EUR 1.4M), following an increase in DARPA funding and new grants received from the European Innovation Council and SMEs Executive Agency (EISMEA) and Eurostars. The new grants received will focus on brain-computer interfaces to reverse upper- and lower-limb paralysis as well as closed-loop control of blood pressure for people with SCI.

### Research & Development Expenses

Research & development expenses increased by 24% from EUR 10.6M in 2021 to EUR 13.1M in 2022 driven by advancements made on our ARC$^{EX}$ and ARC$^{IM}$ platforms, as described in the operational review.

Research & development expenses consist of product development, engineering to develop and support our products, testing, consulting services, and other costs directly attributable to the ARC technology platforms and related therapies. These expenses primarily include salaries for research and development staff and related expenses, including expenses for share-based compensation, and outsourced development expenses. These expenses do not meet the criteria for capitalization given the status of development activities.

Research & development expenses also include the costs of sponsored research activities that are undertaken by universities with which ONWARD collaborates. Since its inception, the Company has had a close working relationship with two of the founders of the Company, Grégoire Courtine, Professor at EPFL and Jocelyne Bloch, Neurosurgeon at CHUV, Professor at Université de Lausanne.

### Clinical & Regulatory Expenses

Clinical expenses increased by 19% from EUR 4.8M in 2021 to EUR 5.7M in 2022 due to the support of the clinical activities. Clinical expenses in 2022 primarily relate to the completion of the Up-LIFT pivotal and LIFT Home clinical trials. Other clinical activities included consulting services and costs associated with first in human implant of ONWARD's IPG and the treatment of 10 people across different ongoing studies for the regulation of blood pressure with ARC$^{IM}$ Therapy. These expenses include employee salaries and related expenses, including share-based compensation, clinical trial management and monitoring, payments to clinical investigators, data management, and travel expenses to the various clinical trial locations.

### Marketing & Market Access Expenses

Marketing and Market Access expenses increased by 33% from EUR 1.5M in 2021 to EUR 2.0M in 2022. Costs incurred related to market access investigative activities in Europe and the US, attendance of key events to create awareness within the SCI community of our ARC therapies and technology, salary costs including related expenses and share-based compensation.

### Patent Fees & Related Expenses

Patent Fees and Related Expenses consist primarily of costs associated to obtaining and maintaining patents and other intellectual property included in ONWARD's growing portfolio. Patent fees & related expenses amounted to EUR 1.5M in 2022 and were at a similar level as in 2021 (EUR 1.4M).

### Quality Assurance Expenses

Quality Assurance expenses increased by 20% from EUR 1M in 2021 to EUR 1.2M in 2022. The efforts are used to strengthen the Company's capability to meet quality and regulatory requirements in support of upcoming regulatory submissions and expected commercialization. Quality Assurance expenses include employee salaries and related expenses, including share-based compensation, consulting, testing and travel expenses related to quality and risk assurance activities.

### General & Administrative Expenses

General and Administrative expenses decreased by 2% from EUR 10.7M in 2021 to EUR 10.6M in 2022. General and Administrative Expenses include employee-related expenses, including salaries, benefits and stock-based compensation; professional fees for auditors and consulting expenses not related to research and development activities; professional fees for lawyers not related to the filing, prosecution, protection and maintenance of our intellectual property; and the cost of facilities, communication and office expenses.

### Net Finance Expense

The Net Financial expense decreased by 74% from EUR 5.7M in 2021 to EUR 1.5M in 2022. The 2021 expense included the interest on the Company's sources of funding from our innovation loan from Riksdienst voor Ondernemend (RVO, a Dutch government funding vehicle for entrepreneurial ventures), our convertible loan (CLA), and the accrued dividend of preference A shares. Both the CLA and preference A shares converted to ordinary shares in October 2021. The 2022 expense is related to the innovation loan from RVO NL plus bank interest paid on our positive cash balance.

### Income Tax Expense

The movement in the Income Tax expense line is mainly the result of the recognition of a deferred tax asset relating to the net operating losses in the US entity to offset the reversable temporary difference recognized as part of the PPA in 2019.

### Net Cash Position

The Company ended the year with a positive net cash balance of EUR 61.8M (2021: EUR 89.4M). This comprises of Cash and cash equivalents of EUR 41.8M and fixed term deposits of EUR 20M.

The table below summarizes the cash flows of the Company for the years 2022 and 2021.

| EUR' Million | 2022 | 2021 |
|---|---|---|
| Net cash generated / (used) from operating activities | **(26.7)** | **(19.9)** |
| Net cash generated / (used) from investing activities | **(20.4)** | **(2.3)** |
| Net cash generated / (used) from financing activities | **(0.6)** | **105.4** |
| Effect of exchange rates on cash and cash equivalent | **(0.0)** | **(0.1)** |

The cash outflow from operating activities increased from EUR 19.9M in 2021 to EUR 26.7M in 2022. The increase of cash used was attributable to higher operating costs as explained above, offset by a decrease in non-cash adjustments (relating to share-based compensation and net finance costs) and a positive change in working capital.

Cash flow from investing activities in 2022 reflects the fixed term deposit investments as well as the acquisition of property, plant, and equipment and the capitalization of ongoing license fee payments to UCLA and Caltech.

The cash inflow in 2021 was the result of the proceeds from the IPO in October 2021 and the convertible loan financing in April 2021. No financing activities occurred in 2022 and the movement in 2022 represents the payment of the lease liability.

The effect of exchange rates did not have a material impact in 2022.

### Interest-Bearing Loans

Interest-bearing loans increased from 31 December 2021 by EUR 1.2M. This is due to the interest that accumulated on the innovation loan from RVO NL (Dutch government).

### Equity

The Company's equity at the end of 2022 remained positive at EUR 52.6M, decreasing with EUR 30.1M from the previous year. The movement is due to the loss for period of EUR 32.7M, adjusted for share-based compensation of EUR 1.7M and the actuarial gain on the remeasurement of post-employment benefits EUR 0.5M and currency translation differences EUR 0.4M.

# 2023 Outlook

We expect to achieve several important milestones in 2023:

**Innovation, Clinical, & Regulatory Developments**

- We plan to submit a de novo application for FDA clearance for our ARC$^{EX}$ system this year, which we anticipate will result in marketing authorization to commercialize that platform in the US in late 2023. We aim to obtain CE mark and European authorization in the same period.
- We intend to publish detailed results from our Up-LIFT Study, for which we announced positive top line data in 2022.
- We expect first-in-human use of our ARC$^{IM}$ Lead, a purpose-designed lead that is optimized for placement along the spinal cord to stimulate the dorsal roots to restore mobility and autonomic function after SCI.
- We plan to begin implants using ARC$^{BCI}$, our brain-computer interface platform for restoration of movement. This program is supported by a grant from the European Innovation Council.

**Corporate**

- We anticipate our current cash position will fuel operations through the end of 2024. In 2023, we plan to pursue opportunities to further strengthen our cash position to support future investments in product development, clinical trials, operational capabilities, and commercial capabilities.
- We plan to continue to build our organizational capabilities in preparation for expected launch of ARC$^{EX}$ late this year, recruiting field sales and service professionals and adding operational systems that will enable us to conduct commerce once we receive FDA clearance and CE mark for our ARC$^{EX}$ system as anticipated later this year. We will also continue to recruit outstanding leaders with global experience and functional expertise who can help us scale effectively and realize our significant potential as a business.

# Governance

## General

ONWARD is a public limited liability company established under the laws of the Netherlands, with common shares listed on Euronext Brussels and Euronext Amsterdam. The Group is composed of ONWARD Medical N.V. (incorporated as a private limited liability company (B.V.) on 20 November 2015) and its wholly owned subsidiaries:

- ONWARD Medical S.A. (Swiss subsidiary established on 12 December 2014)
- ONWARD Medical Inc. (US subsidiary established on 13 September 2013)

The Company and its subsidiaries act as one company, developing both an Implantable Neuro-stimulation System and a non-invasive system for electrical stimulation of specific areas of the spinal cord.

ONWARD's corporate governance is guided by the rules and principles set out in the Dutch 2016 Corporate Governance Code (the CGC), the Company's Articles of Association (AOA) and Dutch law. The AOA are available on the ONWARD website (onwd.com) under the Investors/Governance tab.

## Governance Framework

The Company's overall governance framework and key governance elements at each level are the following:

- For shareholders: the Articles of Association and Shareholder Dialogue policy
- For the Board: the Board Rules, the Charter of the Audit Committee, the Charter of the Compensation Committee, and the Charter of the Nomination Committee

## Board of Directors

ONWARD has a one-tier board consisting of one or more executive directors (uitvoerend bestuurders) and one or more non-executive directors (niet-uitvoerend bestuurders), all of whom are individuals. Our CEO, as Executive Director, with the support of the Management Team, is charged primarily with the Company's day-to-day business and operations and the implementation of the Company's strategy. The non-executive Directors are primarily responsible for supervising the performance of the Executive Director.

Whereas, in a two-tier governance structure, supervisory and management roles are divided between two corporate bodies, in a one-tier governance structure such as that adopted by ONWARD, non-executive Directors and Executive Directors share responsibility for managing the company for those tasks and duties that are not delegated to one or more other specific Directors by virtue of Dutch law, the Articles of Association, or any other arrangement catered for therein (e.g., the Rules of the Board). It is therefore important that the Board ensure sufficient independent supervision by non-executive Directors.

In accordance with the CGC, the Board's role is to provide leadership and supervision to the Company on matters of strategy, risk management, and policies. It has overall responsibility for the management and control of the Company and is authorized to take all actions it deems necessary to achieve the Company's purpose.

In performing their duties, Directors must be guided by the best interests of the Company and its stakeholders, including business partners, employees, and shareholders. The Board has drawn up Rules concerning its organization, decision-making, and other internal matters. These Rules are available on the ONWARD website (onwd.com) under the Investors/Governance tab.

The composition of the Board aims to ensure a broad diversity of experience, knowledge, and skills. The directors are appointed by the Company's Annual General Meeting of shareholders upon nomination by the Board. The general meeting may dismiss a Director at any time by a two-thirds majority vote if less than half of the issued share capital is represented at the General Meeting, unless the resolution for dismissal is passed at the Board's proposal.

Dutch law does not set a limit on the maximum number of consecutive terms that a Director may serve. According to the CGC, non-executive Directors may be elected for a maximum of two consecutive four-year terms and, subsequently, for a maximum of two consecutive two-year terms.

The Board meets as often as any Director considers necessary or appropriate. Resolutions are passed by a simple majority of votes cast. In the case of a tie in the vote of the Board, the resolution is not passed. Any resolutions concerning a material change to the character or identity of the Company or its business must be submitted to the Annual General Meeting for approval.

**Composition of the Board of Directors**

The Company has a one-tier Board consisting of nine members.

| Name | Year of Birth | Nationality | Gender | Position | Year Appointed | End of Term |
|---|---|---|---|---|---|---|
| **Jan Øhrstrøm** | 1957 | Danish | Male | Independent Non-Executive Director & Chairperson | 2016 | Annual General Meeting of 2024 |
| **Dave Marver** | 1968 | American | Male | Executive Director & CEO | 2020 | Annual General Meeting of 2025 |
| **Grégoire Courtine** | 1975 | French | Male | Non-Executive Director & CSO | 2016 | Annual General Meeting of 2023 |
| **Ian Curtis** | 1968 | British | Male | Independent Non-Executive Director & Vice-Chair | 2019 | Annual General Meeting of 2025 |
| **Fredericus Colen** | 1952 | Dutch | Male | Independent Non-Executive Director | 2017 | Annual General Meeting of 2025 |
| **Regina Hodits** | 1969 | Austrian | Female | Non-Executive Director | 2016 | Annual General Meeting of 2023 |
| **John de Koning** | 1968 | Dutch | Male | Non-Executive Director | 2016 | Annual General Meeting of 2024 |
| **Kristina Dziekan** | 1968 | German | Female | Independent Non-Executive Director | 2022 | Annual General Meeting of 2026 |
| **Vivian Riefberg** | 1960 | American | Female | Independent Non-Executive Director | * | * |

**Interim Director (expected to be nominated for appointment as Director at our 2023 Annual General Meeting)*

## Board Members' Biographies

**Jan Øhrstrøm** has more than 30 years' experience in the medical technology and pharmaceutical industries, with a proven track record driving successful product approvals, private financings, and IPOs. He has held senior management roles at NovoNordisk, ProFibrix B.V., and ZymoGenetics, among others. He is currently CEO of VarmX B.V., a company specializing in blood clotting agents, and is chairman of Blaze Bioscience Inc. He holds an MD from the University of Copenhagen. Jan is the Board Chair, Chair of the Compensation Committee, and Chair of the Nominating and Corporate Governance Committee.

**Dave Marver** (CEO) is an accomplished chief executive and director with more than 25 years' international experience in public, private, and emerging companies. He combines expertise in medical and consumer technology, wearables, and health monitoring. Previously, Dave spent almost 15 years with Medtronic, holding a variety of leadership positions in the US and Europe, including vice-president roles in sales, marketing, strategy, and business development. He then joined Nasdaq-listed Cardiac Science Corporation as CEO before co-founding two startups. He holds a BA in psychology from Duke University and an MBA from University of California, Los Angeles.

**Grégoire Courtine** is a full-time professor of neuroscience and neurotechnology at EPFL and Director of .NeuroRestore, a research center at EPFL and CHUV that develops innovative therapies using neurostimulation and other approaches. His ground-breaking research in neuroscience has been recognized by prestigious prizes including the Rolex Award, Schellenberg Research Prize, and Chancellor's Award of the University of California. He holds a PhD in neurosciences from INSERM, Paris, and a PhD in medicine from the University of Pavia, Italy. As a founding Board member, Grégoire serves as a non-executive Director in addition to his role as CSO.

**Ian Curtis** is a member of the Board of the Christopher and Dana Reeve Foundation and the International Spinal Research Trust. As the father of a young woman living with SCI, Ian is deeply committed to advancing research and treatment for SCI. He holds a BA in history from Durham University, is a fellow of the Institute of Chartered Accountants in England and Wales, former partner with PwC and Chairman of HPC plc. Ian is the Board Vice-Chair and Chair of the Audit Committee.

**Fred Colen** has more than 40 years' experience in the medical device industry, with a track record of building strong organizations to bring new technology to market. Fred is President and CEO of Neovasc Inc., a Canadian publicly traded company developing products for the cardiovascular marketplace. Previously, he held senior executive roles at Boston Scientific and St Jude Medical. He holds Master's degrees in Electrical Engineering and Medical Technology from RWTH Aachen University, Germany. Fred is a Member of the Audit Committee and the Compensation Committee.

**Regina Hodits** has more than 20 years' experience in venture capital and is a managing partner at Wellington Partners Life Science Venture Capital Consulting GmbH, where she focuses on early-stage and growth investments. Before joining Wellington, Regina led the European life sciences efforts of Boston-based Atlas Venture. She was a founding investor in Bicycle Therapeutics, F-star, and JenaValve, and currently serves on the boards of Ayoxxa, Carisma, Sidekick, SNIPR Biome, and Stipe. Regina holds a PhD in biochemistry from the Technical University of Vienna. She is a Member of the Nominating and Corporate Governance Committee.

**John de Koning** is a General Partner at EQT Group (formerly LSP), one of the largest European investment firms providing financing for life sciences and health care companies. Since joining EQT Group in 2006, John has led some of its most successful investments and served on the board of several companies, including argenx, Merus, and Prosensa. He holds an MS in molecular biology from the University of Utrecht and a PhD in oncology from the Erasmus University Rotterdam. John is a Member of the Nominating and Corporate Governance Committee.

**Kristina Dziekan** is currently Head of Market Access, Government Affairs, and Tendering for Alcon's Surgical Division in Europe. She previously served as Senior Global Reimbursement and Health Economics Director for Medtronic Neuromodulation and was Health Outcomes Manager for GlaxoSmithKline in the UK and parts of Asia. She earned an MSc in health policy, planning, and financing from the London School of Economics, an MA in international economics and European Studies from Johns Hopkins University, a BA in philosophy, politics, and economics from Oxford University, and a Vordiplom in business administration and economics from Georg August University. Kristina is a Member of the Audit Committee.

**Vivian Riefberg** is currently the David C. Walentas Jefferson Scholars Chair Professor of Practice at the Darden School of Business at the University of Virginia and serves on the boards of Signify Health, K Health, and Lightrock, an impact investing firm, as well as of the Public Broadcasting System (PBS), Johns Hopkins Medicine, the Lorna Breen Heroes Foundation, and the National Education Equity Lab. She is also an advisory board member for the Smithsonian's planned American Women's History Museum. She retired from McKinsey & Company in 2020 after 31 years. At McKinsey, she served as co-leader of the US healthcare practice and leader of the public sector practice. She also served on McKinsey's global board of directors. She previously served on the US National Institutes of Health (NIH) Clinical Center Board of Governors and the NIH Advisory Board for Clinical Research. She also served on the Board of Directors of the Partnership for a Healthier America (PHA), a non-profit organization created to mobilize efforts to solve the child obesity challenge as an outgrowth of First Lady Michelle Obama's Let's Move campaign. She holds a BA, magna cum laude in history from Harvard-Radcliffe College and an MBA with distinction from Harvard Business School. Vivian is a member of the Compensation Committee.

### Director Independence

In accordance with best practice provision 2.1.7 of the CGC, the majority of the non-executive directors must be independent and at most one non-executive Director does not have to meet the independence criteria. A Board member is considered "not independent" if he or she, a spouse, partner, or close family member (related by blood or marriage up to the second degree) meet any of the conditions listed below:

- Has been an employee or member of the management board of the Company, including associated companies (as referred to in Section 5:48 of the Financial Supervision Act Wet op het financieel toezicht/ Wft) in the five years prior to their appointment.
- Receives personal financial compensation from the Company, or an associated company, other than the compensation received for the work performed as a Board member.
- Has had an important business relationship with the Company or an associated company in the year prior to the appointment.
- Is an executive of a company in which a member of the management board of the company which he supervises is a non-executive Board member.
- Has temporarily performed management duties during the previous twelve months in the absence or incapacity of a member of the management board.
- Has a shareholding in the company of at least 10%.
- Is a member of the management board or supervisory board, or a representative in some other way, of a legal entity that holds at least 10% of the shares in the company, unless the entity is a group company.

At the date of this Annual Report, the Board consists of eight members and one interim director, seven of the eight are non-executive directors. The interim director is also considered, non-executive. Three of these non-executive directors are deemed "not independent" based on meeting certain of the conditions above. Prof. Courtine, one of the Company's founders, is considered "not independent" as he is the Chief Science Officer of the Company and receives personal compensation for such a role. Regina Hodits and John de Koning are considered "not independent" as they are representatives of major shareholders holding at least 10% of the shares in the Company (Wellington and EQT Group (formerly LSP). The requirements for independence as per best practice provision 2.1.7 of the CGC are met.

### Committees within the Board of Directors

The Board has established the following three committees:

- the Audit Committee
- the Compensation Committee
- the Nomination and Corporate Governance Committee

Non-executive directors are appointed to committees by the Board. The committees report their findings to the Board, which is ultimately responsible for all decision-making. The role, responsibility and functioning of each committee is summarized below.

## Audit Committee

The Audit Committee comprises three members: Ian Curtis (Chair), Fred Colen and Kristina Dziekan.

In accordance with its charter, the Audit Committee is charged with the following matters:

a. Monitoring the Board with respect to:
   - relations with the internal audit function and the external auditor, as well as compliance with recommendations and follow-up of comments
   - the Company's funding
   - the application of information and communication technology by the Company, including risks relating to cybersecurity
   - the Company's tax policy

b. Issuing recommendations concerning the appointment and the dismissal of the head of the internal audit function, as relevant, and reviewing and discussing the performance of the internal audit function.

c. Reviewing and discussing the Company's audit plan, including with the internal audit function and the external auditor.

d. Reviewing and discussing the essence of the audit results, also with the internal audit function, including:
   - flaws in the effectiveness of the Company's internal risk management and control systems ("Internal Controls")
   - findings and observations with a material impact on the Company's risk profile
   - failings in the follow-up of recommendations made previously by the internal audit function

e. Monitoring the audit of the Company's annual accounts, annual report and financial reporting processes, and making proposals to safeguard the integrity of these processes.

f. Reviewing and discussing the effectiveness of the design and operation of the Internal Controls with the Board, the CEO and the CFO, including identified material failings in the Internal Controls and material changes made to, and material improvements planned for, the Internal Controls.

g. Reviewing and monitoring the independence of the external auditor, also considering any non-audit services rendered by the external auditor.

h. Submitting proposals to the Board concerning the external auditor's engagement to audit the Company's financial statements, including the scope of the audit, the materiality standard to be applied and the external auditor's fees.

The members of the Audit Committee are appointed and dismissed by the Board. More than half of all its members, including the chairperson, must be independent within the meaning of the CGC and at least one committee member must have competence in accounting and/or auditing.

The Audit Committee shall meet as often as it determines is appropriate to carry out its responsibilities and each meeting shall be presided over by the chairperson and, in the absence of the chairperson, one of the other members shall be designated as the acting chairperson of the meeting.

ONWARD has not yet established a separate internal audit function and the related responsibilities as per the charter does not apply.

### Compensation Committee

The Compensation Committee comprises three members: Jan Øhrstrøm (Chair), Fred Colen and Vivian Riefberg. In deviation from best practice provision 2.3.4/5.1.4 of the CGC, the Compensation Committee is led by Jan Øhrstrøm, who is also Chairperson of the Board. (Refer to 'Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code'.). The Board considers that the experience and continuity of Dr. Øhrstrøm being chair of the Compensation Committee outweighs the disadvantages of him holding both positions.

In accordance with its charter, the Compensation Committee is charged with the following matters:

a. Submitting proposals to the Board concerning changes to the Company's compensation policy.

b. Submitting proposals to the Board concerning the compensation of individual directors, covering:

   - compensation structure
   - amount of the fixed and variable compensation components
   - applicable performance criteria
   - scenario analyses that have been carried out
   - pay ratios within the Company's group
   - views of the director concerned regarding the amount and structure of his or her own compensation

c. The preparation of the Company's compensation report for the Board.

### Nomination and Corporate Governance Committee

The Nomination and Corporate Governance Committee comprises three directors: Jan Øhrstrøm (Chair), John de Koning and Regina Hodits. Jan Øhrstrøm serves as Chairperson of the Nomination and Corporate Governance Committee. In deviation from the CGC more than half of the committee members are not "independent" within the meaning of the Code, namely John de Koning and Regina Hodits. (Refer to Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code). The Board considers that the experience and continuity of Dr. de Koning and Dr. Hodits outweigh the disadvantages of these deviations from the CGC.

In accordance with its charter, the Nomination and Governance Committee is charged with the following matters:

d. Drawing up selection criteria and appointment procedures for the directors.

e. Reviewing the size and composition of the Board and submitting proposals for the composition profile of the Board.

f. Reviewing the functioning of individual directors and reporting on such reviews to the Board.

g. Drawing up a plan for the succession of directors.

h. Submitting proposals for (re)appointment of directors.

i. Supervising the policy of the Board regarding the selection criteria and appointment procedures for the Company's senior management and executive officers

## Management Team*

The Management Team is responsible for running the Company in accordance with the strategies, policies and budgets determined by the Board. It has all powers except for those reserved for the Board and the General Meeting of shareholders by law and by the Company's Articles of Association.

The members of the Management Team commit to carrying out their duties in accordance with the highest business, ethical, moral, and legal standards laid out in the Company's Code of Business Conduct and Ethics (see onwd.com, Investors/Governance). They strive to lead by example by embodying the ONWARD code of values in everything they do. The Management Team meets at least once a week.

| Name | Position | Member Since |
|---|---|---|
| **Dave Marver** | Chief Executive Officer | 2020 |
| **Grégoire Courtine** | Chief Science Officer | 2016 |
| **John Murphy** | Chief Technology Officer | 2020 |
| **Lara Smith Weber** | Chief Financial Officer | 2022** |
| **Hendrik Lambert** | VP Clinical & Regulatory | 2016* |
| **David Harari** | Managing Director U.S.A | 2019* |
| **Andy Dolan** | VP Marketing | 2021 |
| **Rano Burkhanova** | Global HR Director | 2020 |
| **Zouhir Mechta** | VP Operations | 2022 |

** In Q1 2023, Erika Ross Ellison joined as VP Global Clinical & Regulatory and Sarah Moore joined as VP Global Marketing, with Andy Dolan moving into the VP Sales role. Hendrik Lambert and David Harari stepped down from their respective roles in Q1 2023.*
*** Lara Smith Weber joined as CFO on 1 June 2022, succeeding Marko Jansen who stepped down 30 June 2022.*

## Biographies of the Management Team

**Dave Marver** (see biography p. 114).

**Grégoire Courtine** (see biography p. 114).

**John Murphy** has over 25 years of experience driving the development of medical implants and neurostimulation devices at LivaNova, Abbott, and Medtronic. His leadership expertise spans the continuum of R&D, with a focus on consumer-centric design, IP generation, and agile processes. Prior to joining ONWARD in 2020, John was the Chief Technology Officer of LivaNova Neuromodulation. He holds a BS in electrical engineering from the University of North Carolina at Charlotte and a PhD in production systems and robotics from EPFL.

**Lara Smith Weber** has over 20 years of experience in finance, accounting, and strategy for publicly traded life science entities in the US and Europe. Before joining ONWARD, Lara served as CFO for MorphoSys, Inc. and Senior VP Controlling and Corporate Finance at MorphoSys AG in Munich, where she led a Nasdaq IPO. Previously, Lara held a variety of finance leadership positions at Telefonica Germany and worked for the consulting firm, Booz Allen Hamilton, in Zurich, Switzerland. Lara holds a BA in German studies, a BS, an MSc in electrical engineering from Stanford University, and an MBA from IMD in Lausanne.

**Hendrik Lambert** has over 20 years of experience leading clinical and regulatory strategies for high-risk (Class III) medical devices in Europe and the US, from initial design to market approval. Before joining ONWARD in 2015, Hendrik was Vice President for Clinical and Regulatory Affairs at Endosense, a Geneva-based medtech company developing innovative products for the cardiology market, which was acquired by St. Jude Medical. He holds a PhD in biomedical engineering from the University of Ghent, Belgium.

**David Harari** is a scientific leader with 30 years of experience in the clinical and regulatory management of medical devices, from initial concept to commercialization. Before joining ONWARD in 2019 to lead its US affiliate, David held senior positions in clinical affairs with Guidant, Boston Scientific, Endosense, St. Jude Medical, and Vytronus Inc. He holds a BS in engineering sciences and biomedical engineering from the University of Michigan.

**Andy Dolan** has 20 years of experience in marketing, business development, and organizational leadership at medical device companies, both private and public. Before joining ONWARD in 2021, Andy held senior roles in sales and marketing at ReWalk Robotics, Boston Scientific, Johnson & Johnson, and Integra LifeSciences. He holds an MBA from the University of Massachusetts and a graduate certificate in bioengineering from Tufts University. He also serves as a United States Navy Reserve Public Affairs Officer.

**Rano Burkhanova** is an accomplished talent development executive with 15 years of experience with multinational companies in the US and the Netherlands. Before joining ONWARD in 2020, Rano managed leadership development, talent management, gender diversity, and engagement programs for Danone Nutrition, Elsevier, and Medtronic. She holds an MA in human resources management from Cornell University and an MBA from the Quantic School of Science and Technology.

**Zouhir Mechta** has over 20 years of progressive experience with leading companies such as Johnson & Johnson, Dentsply Sirona, and Nestlé. He previously served as Vice President of Manufacturing and Supply Chain for Dentsply Sirona for the US, EMEA, and Switzerland. He also has experience with scale-up companies and has overseen multiple ERP system installations, established manufacturing systems, and built procurement and customer service capabilities. He holds a Master's degree in process management from the University of Technology Belfort Montbéliard and a Bachelor's degree in mechanical engineering from the Technology Institute F. Buisson.

### Diversity

The Board has adopted a diversity policy which became effective on the date of first trading. The policy does not define specific targets. It is the ambition that both the Board and Management Team should comprise one-third of female members, while also ensuring diversity in terms of background, skills, and age. This policy is available on our **website** under the Investors/Governance tab.

The Company made a concerted effort to recruit directors and management members with the skills and background to support the Company's independence and diversity objectives. At the date of this report, ONWARD's Board consists of 6 male directors (1 being an executive director) and 2 female directors (all non-executive directors). The formal appointment of interim director, Vivian Riefberg, at the next AGM will result in a one third female representation on the Board. The Management team consists of 5 male members and 4 female members.

### Conflicts of Interest

According to principle 2.7.4 of the CGC, the Company must report on directors' conflicts of interest in transactions in its management report where the conflict of interest is of material significance to the Company or to the relevant director. Directors and members of management are expected to arrange their personal affairs so as to avoid conflict of interest. Any potential conflict of interest must be brought to the attention of the Board.

Certain directors and members of the Management Team have a direct or indirect beneficial interest in ONWARD's share capital or serve as a representative of a legal entity that is a major shareholder. In their capacity as non-executive directors, their primary duty is to supervise the performance of the executive directors and the management of the Company and its business. A conflict of interest may arise if a decision aimed at contributing to the Company's long-term and sustainable success negatively impacts its share price in the short term, thereby reducing the value of the shareholding of which the non-executive director is a representative.

As of 31 December 2022, the potential conflicts of interests between the duties to the Company of each of the directors and members of the Management Team and their private interests or other professional duties were as follows:

a. Grégoire Courtine is the Chief Science Officer and a Non-Executive Director of the Company.

b. John de Koning represents LSP V Coöperatieve U.A., a major shareholder of the Company and Non-Executive Director of the Company.

c. Regina Hodits represents Wellington Partners Life Science Venture Capital Consulting GmbH, a major Shareholder of the Company and Non-Executive Director of the Company.

No transactions that would result in a conflict of interest were reported to the Board in 2022.

**Related Party Transactions**

While ONWARD does not have a related party transaction policy, it complies with the recommendations of the Dutch Civil Code (DCC) in this respect.

The Dutch act to implement the EU Shareholder Rights Directive II (Bevordering van de langetermijnbetrokkenheid van aandeelhouders, "Dutch SRD Act") which entered into force on 1 December 2019, added new rules on related party transactions to the DCC. These rules stipulate that "material transactions" with "related parties" that are not entered into within the ordinary course of business or not concluded on normal market terms must be approved by the Board and be publicly announced at the time of or before the transaction takes place. The Board is required to establish an internal procedure to periodically assess whether transactions with related parties are concluded in the ordinary course of business and on normal market terms.

In particular, all transactions between ONWARD and a shareholder holding 10% or more of issued share capital should be agreed on customary terms. Decisions to enter into such a transaction that is of material significance to the Company and/or to the Shareholder concerned should be approved by the Board. Any such transaction should be disclosed in the Company's Board report, together with an affirmative statement that these recommendations of the Code have been complied with.

No related party transactions with a shareholder holding 10% or more of the issued share capital were reported to the Board in 2022.

**General Meeting**

The main powers of the General Meeting relate to:

- the issuance of shares or rights to shares, restriction or exclusion of pre-emptive rights of shareholders, repurchase of shares and reduction of the issued share capital
- the amendment of the Articles of Association
- the appointment, suspension and dismissal of members of the Board
- decisions of the Board involving a significant change in the Company's identity of character
- the approval of the remuneration policy of the Board
- the adoption of the Financial Statements and declaration of dividends
- the appointment of the Company's external auditor

The Annual General Meeting is held within six months after the end of the financial year to discuss and, if applicable, approve, the Annual Report, the Annual Accounts and any of the other topics mentioned above.

The Annual General Meeting and, if necessary, other General Meetings, are convened by the Board. The agenda and explanatory notes are published on the Company website.

The first Annual General Meeting was held on 10 June 2022. The agenda, explanatory notes and minutes are published on the Company website. The next Annual General Meeting is scheduled for 15 June 2023.

ONWARD's authorized share capital *(maatschappelijk kapitaal)* amounts to EUR 12,225,000 divided into 50,937,500 Ordinary Shares and 50,937,500 Preferred Shares with a nominal value of EUR 0.12 each. At 31 December 2022, 30,184,388 Ordinary Shares represented all issued capital. All of the issued Ordinary Shares are fully paid-up and represent capital in the Company. Each shareholder of the Company is entitled to cast one vote per share in a shareholders' meeting. No shareholders have any voting rights different from any other shareholder.

**Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code**

ONWARD acknowledges the importance of good governance and is committed to adhering to the best practices of the CGC as much as possible. As of the date of this annual report, we report the following deviations from the CGC:

- **Best practice provision 2.3.4/5.1.4.** The CGC provides that the Compensation Committee should not be chaired by the Chairperson of the Board. In deviation from the CGC, the Compensation Committee is chaired by the Chairperson of the Board. The Board considered that the experience and continuity of Jan Øhrstrøm being chairperson of the Compensation Committee outweighs the disadvantages of him also being the Chairperson of the Board. For the reasons provided, the Company does not intend to fully comply with this best practice provision.
- **Best practice provision 2.3.4.** The CGC provides that more than half of the members of the Committees should be independent within the meaning of best practice provision 2.1.8. The Nomination and Corporate Governance Committee consists of three directors: Jan Øhrstrøm (chair), John de Koning, and Regina Hodits. In deviation from the CGC more than half of the committee members are not "independent" within the meaning of the Code, namely John de Koning and Regina Hodits. The Board considered that the experience and continuity of Dr. de Koning and Dr. Hodits outweigh the disadvantages of these deviations from the CGC. For the reasons provided, the Company does not intend to fully comply with this best practice provision.
- **Best practice provision 3.1.2 v** recommends that variable remuneration should be linked to measurable performance criteria determined in advance. To align the employee's interest with the interests of the Shareholders and to allow the participation in the long-term growth of the Company, options were granted to the management team (including the Executive Director). There are no specific performance conditions associated to these options, only a service condition. However, considering that the value of the option is linked to the share price of ONWARD it includes an inherent performance criterion. Furthermore, the size of the stock option is linked to the position and job grade of the individual and is contingent on the performance of the individual. We will consider if more clear measurable performance criteria should be added to future grants.
- **Best practice provision 3.3.2.** The CGC recommends against providing equity awards as part of the compensation of a non-executive director. In 2022, the new Interim Director (Vivian Riefberg) was awarded 16,000 share options under the existing long-term incentive plan as a signing bonus. This deviation was approved by the Board on recommendation of the Compensation Committee. The grant is considered necessary to serve the long-term interests and sustainability of the Company and to assure its viability since such grant is instrumental to attract and retain a highly qualified non-executive director in particular when compared to compensation practices in the US. Our current non-executive director compensation policy does not include an ongoing equity award for any non-executive director and we do not intend to make supplemental equity awards outside of the policy going forward.
- **Best practice provision 3.3.3.** The CGC recommends that shares held by a non-executive director in the company on whose board of directors they serve should be held as a long-term investment. The Company's Compensation Policy does not include such a requirement.
- **Best practice provision 3.4.1iii** The CGC recommends that scenario analyses be taken into consideration in determining the remuneration of the Executive Director. No scenario analysis has been taken into consideration in determining the remuneration of the Executive Director for 2022. The Remuneration Committee will consider performing scenario analyses in 2023.

- **Best practice provision 4.3.3.** The CGC recommends that the General Meeting should be capable of passing a resolution cancelling the binding nature of a nomination or dismissal by simple majority, representing no more than one-third of the issued share capital. Under the Articles of Association, directors can only be appointed or dismissed by the General Meeting by simple majority of votes cast, provided that the Board proposes the appointment or dismissal. In other cases, the General Meeting can only pass a resolution to appoint or dismiss a director by a two-thirds majority representing more than half of the issued share capital. The Company deems this appropriate considering the remaining shareholdings

# Risk Management & Control

Analyzing, monitoring, and managing internal and external risks is crucial to ensuring that we meet our ambitious targets, that our financial information is reliable, and that our activities comply with all applicable laws and regulations. Current risks mainly concern research and development of our ARC therapies, securing regulatory approvals, protecting our intellectual property, and maintaining equity in the Company's mid- to long-term financing.

The Management Team is responsible for developing, implementing, and operating adequate risk-management and internal control systems. The Board has a control function with respect to these systems. Our risk-management and internal control systems are reviewed, updated, and optimized as an ongoing process based on internal evaluations, discussions with the Board and the Audit Committee, and audits from external parties.

The Company initiated its first formalized annual risk review, post IPO, at the end of 2022. The outcome of the review has been incorporated into this report. Although we started engaging consultants to support our increased focus on IT, cybersecurity and formalizing our internal control framework, there were no major changes in the risk management and control systems in the year under review.

As ONWARD has not established a separate internal audit function, the Board annually assesses whether adequate alternative measures have been taken. Based on the Audit Committee's recommendations, Directors may consider whether it is necessary to establish an internal audit function. In 2022, no material failings in the internal risk management and control systems were discovered.

It should be noted that these systems cannot provide absolute assurance that the Company will realize its targets, nor can they prevent all misstatements, errors, and non-compliances with legislation, rules, and regulations.

### Risk Control Matters

Due to its size and history, the Company does not yet have a fully deployed and formalized risk detection, evaluation, and management system in place. The Board and Management Team continuously analyze potential risks, evaluate their (financial) impact and likelihood, and determine appropriate measures to minimize these risks. Risk assessments are updated in line with changing internal and external circumstances.

The Board and Management Team meet regularly to review developments, set targets and milestones, and evaluate progress towards realizing them. During these meetings, they also review ONWARD's financial position and present budgets/cashflow forecasts, which are followed up and regularly adjusted to changing prospects. The Management Team monitors risks as they arise and evolve, assesses their development, and implements necessary countermeasures as required.

To manage our business risks, we use highly experienced staff and external consultants for our research and clinical studies. The results of our studies are monitored constantly, closely, and systematically. This enables us to react early to new findings, and to conduct preclinical and clinical activities. By closely monitoring the costs associated with these activities through our regular internal budget and monitoring processes, we can recognize any deviations from our financial plans early on and initiate appropriate countermeasures.

We are highly dependent on third parties to enable us to meet our regulatory requirements and our own quality standards. We therefore take special care in selecting our contractors. Major clinical trial and component service providers are selected through a stringent selection process driven by the Management Team, in which we assess the quality and experience of several candidates. We constantly review and assess the operational performance of the organizations we work with.

We work with only highly specialized consultants and attorneys to secure and monitor our intellectual property (IP). In addition, the Management Team regularly monitors ongoing patent protection and potential conflicts.

Our risk-management and internal control systems in relation to our financial reporting process is designed to provide reasonable assurance that our books and records accurately reflect the transactions necessary to permit preparation of financial statements; that the financial reporting is consistent and compliant with legal regulations and generally accepted accounting principles; and that published financial data do not contain any material misstatements. The system also provides reasonable assurance that all receipts and expenditures are only made by people authorized to do so and that assets are safeguarded. To manage risks associated with valuation uncertainties we engage specialists with the required skills to assist with these valuations for financial reporting purposes. This includes but is not limited to the valuation of the defined benefit obligation and the determination of the fair value of options granted.

As part of this system, we have adopted various internal rules and regulations, including standard operating procedures, the dual-control principle, spot checks, automated expenses reimbursement tooling, internal contract approval processes, and signatory rules.

### Risk Appetite

Our risk appetite differs according to the various risk categories ONWARD is exposed to, namely:

**Risks related to our business, strategy and industry** include adverse, unexpected developments resulting from internal processes, people, and systems or from our external research partners and external events, which are linked to the operation of the business. We are prepared to take moderate risks to achieve our ambitions and to balance risk and long-term reward.

**Risks related to legal and government regulation** relate to unanticipated failures to comply with applicable laws and regulations. We aim to minimize these risks by aiming to comply fully with these laws and regulations.

**Risks related to intellectual property.** We aim to minimize these risks, only accepting a low level, to ensure that intellectual property is protected.

**Risks related to our financial position, need for additional capital, and taxation** occur in connection with funding, treasury, tax, accounting, and reporting. ONWARD is prudent with respect to these financial risks, with the aim of maintaining long-term solvency. We are committed to transparent and truthful accounting and reporting that allow users of financial statements to make decisions considering these risks. We currently do not engage in any hedging activities. Our financial risk management is set out in note 4.3 of our consolidated financial statements.

**Description of the Principal Risks Associated With the Company's Activities**

The following section describes the main risks and uncertainties that we consider the major threats to achieving our objectives. Additional factors not listed here may also have an adverse effect on our business, financial condition, results of operations, and prospects, and could adversely affect our share price. All of these risks are contingencies which may or may not occur.

**Risks Related to the Company's Business, Strategy & Industry**

*ONWARD wholly depends on the success of two investigational devices, the ARC$^{IM}$ and ARC$^{EX}$ platforms. Even if the Company completes clinical development and obtains favorable clinical results for the initial indications it is pursuing, it may not be able to obtain regulatory clearance or approval for, or successfully commercialize, its ARC$^{IM}$ and ARC$^{EX}$ platforms.*

ONWARD currently has two investigational devices in clinical development — the ARC$^{IM}$ and ARC$^{EX}$ platforms — and our business depends almost entirely on the successful clinical development, regulatory clearance or approval, and commercialization of these investigational devices, which may never occur. We currently have no products available for sale, generate no revenues from sales of products, and may never successfully develop marketable products.

Our ARC$^{IM}$ and ARC$^{EX}$ platforms will require substantial additional clinical development, testing, manufacturing process development, and regulatory clearance or approval before we are permitted to commence their commercialization. For example, before obtaining Premarket Approval Application (PMA) approval from the U.S. Food and Drug Administration (FDA) for our ARC$^{IM}$ platform, we must show, among other things, that the product is safe and effective for use in each target indication, a process that can take many years.

If we opt to seek approval via the FDA's Humanitarian Device Exemption (HDE) pathway for the commercial sale of ARC$^{IM}$, we must show through extensive preclinical testing and clinical trials that the product candidate does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, considering the probable risks and benefits of currently available devices or alternative forms of treatment.

Of the substantial number of medical devices in development in the U.S., only a small percentage successfully complete the regulatory clearance or approval process required by the FDA and become commercialized. Similarly, many medical devices currently in development will ultimately not obtain the certificate of conformity required for commercialization in the European Economic Area (EEA). Therefore, even if we obtain the requisite capital to continue funding our development and clinical programs, we may be unable to successfully develop or commercialize our ARC$^{IM}$ and ARC$^{EX}$ platforms or any other product candidate.

*Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult, or rendered impossible, by multiple factors outside ONWARD's control. This could significantly delay the completion of such trials or may cause the Company to abandon one or more clinical trials.*

ONWARD may encounter delays or difficulties in enrolling — or may be unable to enroll — a sufficient number of patients to complete any of its clinical trials on its current timelines, or at all. Even once candidates are enrolled, the Company may be unable to retain a sufficient number of patients to complete any of its trials.

Patient enrollment in clinical trials, and completion of patient follow-up, depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, eligibility criteria for the clinical trial, patient compliance, competing clinical trials, and clinicians' and patients' perceptions as to the

potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be cleared or approved for the indications we are investigating.

Patients may be discouraged from enrolling in ONWARD's clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate. Patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to its products. Delays in patient enrollment, or failure of patients to continue participating in a clinical trial, may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial or result in failure of the clinical trial.

Since some of the indications that our investigational devices are intended to treat are limited, ONWARD expects only a subset of patients with spinal cord injury (SCI) to be eligible for its clinical trials. The protocols for our clinical trials generally mandate that a patient cannot be involved in more than one clinical trial for the same indication. Therefore, subjects who participate in ongoing clinical trials for products that compete with our investigational devices are not eligible to participate in our clinical trials. ONWARD cannot guarantee that any of its programs will identify a sufficient number of patients to complete clinical development, pursue regulatory clearance or approval, or market its investigational devices, if cleared or approved.

An inability to recruit and enroll a sufficient number of patients for any of its current or future clinical trials would result in significant project delays, or may require us to abandon one or more clinical trials altogether, which could impact ONWARD's ability to develop its investigational devices and may have a material adverse effect on its business, results of operations, and financial condition.

*The Company must obtain FDA clearance or approval before it can sell any of its products in the U.S., and CE Certification before it can sell any of its products in the European Union (EU). Approval of similar regulatory authorities in countries outside the U.S. and the EU is required before it can sell its products in countries that do not accept FDA clearance or approval or CE Certification. The Company may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of its products if such clearance or approval is denied or delayed.*

The development, manufacture, and commercialization of our products are subject to government regulation. In the U.S., Europe, and most other countries, ONWARD must complete rigorous preclinical testing and extensive clinical trials that exhibit the safety and efficacy of our devices before we can apply for regulatory clearance or approval to market them. Regulatory bodies such as the FDA may limit approval to specific indications, restrict the distribution of a device, or refuse to grant clearance for additional or expanded indications, which could limit our potential revenues.

Though we believe that our preclinical and clinical data will be sufficient to support regulatory clearance or approval, if the data we submit is not acceptable to the relevant regulatory authorities, clearance or approval may be delayed or may not be feasible, which could adversely impact our business, time to market, and financial condition.

*If cleared or approved, the Company may not be able to successfully commercialize its ARC$^{EX}$ and ARC$^{IM}$ platforms. Failure to gain market acceptance would impact the Company's revenues and may materially impair its ability to continue its business.*

Even if ONWARD receives regulatory clearances or approvals for the commercial sale of our investigational devices, the commercial success of our products will depend on, among others, their acceptance as a therapeutic and cost-effective alternative to competing products and treatments for people with SCI, by medical professionals working in the rehabilitation clinic setting, such as physicians, physical therapists, occupational therapists, neurologists, and physiatrists, as well as by functional neurosurgeons, patients, third-party payors such as health insurance companies, and other members of the medical community. There can be no assurance that medical professionals, hospitals, and rehabilitation clinics will adopt the use of ARC$^{EX}$ and ARC$^{IM}$ and establish training and procedures to implement them. Market acceptance of, and demand for, any product we may develop and commercialize will depend on many factors, both within and outside of our control. Payors may view new or recently launched products, or products where limited clinical data is available, as investigational, unproven, or experimental, and on that basis

may deny coverage of procedures involving use of these products or require additional clinical trials and data before providing coverage. If our investigational devices fail to gain market acceptance, ONWARD may be unable to earn sufficient revenue to continue our business.

*If ONWARD obtains clearance or approval for its products, their commercial success will depend in part on the level of reimbursement it receives from third parties for the cost of its products to users.*

In most markets, third parties such as health insurers, government-managed health care schemes, or managed care organizations decide which treatments they will cover and how much of the cost they will reimburse. These reimbursement systems vary widely, meaning that approval for reimbursement must be obtained on a country-by-country basis. ONWARD's business could be adversely affected if hospitals or other users are not able to obtain and maintain coverage and adequate reimbursement for procedures using our devices.

Additionally, third-party payers, especially in the United States, are increasingly examining not only product safety and effectiveness but also their cost effectiveness when making coverage and payment decisions. It is uncertain whether the Company's current products, or any planned or future products, will be viewed as sufficiently cost effective to warrant coverage and adequate reimbursement levels in any given jurisdiction.

*If its investigational devices are cleared or approved, the Company will need to receive access to hospital facilities and clinics, or its sales may be negatively impacted.*

In the United States, in order for physicians or clinicians to use ONWARD's products, we expect that the hospital facilities or clinics where these physicians or clinicians treat patients may require us to enter into purchasing contracts. This process can be lengthy and time-consuming and can require extensive negotiations and management time. In Europe, certain institutions may require us to engage in a contract bidding process if the expected purchase commitments exceed specified cost thresholds, which vary by jurisdiction. If ONWARD does not receive access to hospital facilities or clinics via these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, our sales and operating results may be negatively impacted.

*The Company relies on a limited number of third-party suppliers and contract manufacturers to produce and assembly its products. Loss or degradation in performance of these suppliers and contract manufacturers could have a material adverse effect on its business, financial condition, and results of operations. Reliance on a limited number of third-party suppliers and in some cases single-source suppliers, makes the Company vulnerable to supply shortages and problems and price fluctuations, which could further harm our business.*

We rely on a limited number of third parties, some of whom are sole suppliers, to purchase materials and components, and/or to manufacture and assemble our ARC$^{EX}$ and ARC$^{IM}$ platforms. Our ability to supply our products for clinical trials and, ultimately, to market them and to develop future products, depends on the availability of sufficient quantities of materials, components, and manufacturing services that meet regulatory requirements. While we seek to maintain sufficient levels of inventory at all times, this may not fully protect us from supply interruptions.

Our suppliers and contract manufacturers have generally met our demand for their products and services on a timely basis. However, relationships with suppliers may be disrupted due to a number of factors, such as unforeseen events that delay production or a decision by either party to terminate the relationship.

If that occurs, we are confident that we will find alternative suppliers to meet all our needs. However, due to the relatively low volume of orders and the bespoke nature of our requirements, establishing new relationships would be a time-consuming and expensive process. We would need to verify that the new supplier or third-party manufacturer maintains their facilities, procedures, and operations in accordance with ONWARD's quality standards and all applicable regulatory requirements. In addition, our contract manufacturers could require that we move production to a different facility or use alternative materials or components. Any of these events could require us to modify the designs or specifications of our products, and to secure new regulatory approval before implementing the change, which could result in further delay or a refusal to grant clearance.

*If there are quality issues, or if the performance of its products does not meet the expectations of physicians or patients, the Company may be subject to claims and liability, and its brand, reputation, and business could be adversely affected.*

In the course of conducting our business, ONWARD must adequately address quality issues that may arise with the ARC$^{EX}$ and ARC$^{IM}$ systems, including defects in third-party components included in its products. Additionally, even if free of quality issues, our products may not meet the expectations of physicians or patients with respect to achieving desired results.

The internal procedures designed to minimize risks that may arise from quality issues may not sufficiently eliminate or mitigate occurrences of these issues and associated liabilities. Moreover, even in the absence of quality issues, we may be subject to claims and liability if our products' performance does not meet expectation of physicians or patients in both clinical and commercial settings.

*The Company relies on relationships with academic research centers to support its research and development activities and may not be able to enhance its product offerings through its research and development efforts.*

ONWARD's primary research partnership is with .NeuroRestore, a joint initiative of L'École polytechnique fédérale de Lausanne (EPFL) and Le Centre hospitalier universitaire vaudois (CHUV) in Lausanne, Switzerland, with whom we have an exclusive IP and commercialization license agreement. We also have relationships with several leading research universities around the world, including California Institute for Technology (Caltech), the University of California at Los Angeles (UCLA), and the University of Louisville (U.S.A) and the University of British Columbia (Canada).

.NeuroRestore's conducts ground-breaking research ranging from basic and preclinical research all the way to human proof-of-concept studies. ONWARD will select the most promising projects developed by .NeuroRestore to develop and commercialize, primarily based on clinical results and commercial viability. If our relationships with .NeuroRestore or our other academic partners were to be terminated or otherwise modified, it could adversely affect our ability to expand potential indications for ARC Therapy in future. Grégoire Courtine, ONWARD's Chief Science Officer, is a professor at EPFL. If this potential conflict of interest is not prudently managed, it could adversely affect our ability to license intellectual property from EPFL and commercialize therapies that rely on that IP.

ONWARD may also decide to invest in developing new partnerships and licensing agreements to provide us with new product offerings without significant research and development activities. However, these agreements may not give us exclusive rights to use the intellectual property for all relevant fields of use or territories where we wish to develop or commercialize our products. As a result, we may not be able to prevent other companies from developing and commercializing competing products. Moreover, if these licenses were terminated, competitors would have the freedom to develop products similar or identical to ours.

Despite thorough market research, our products may not incorporate all the features sought by consumers, their caregivers, or their healthcare providers. We may also experience delays in various phases of product development that cause customers to delay or forgo purchase of our devices. Even if we successfully develop these products, they may not generate sales in excess of the costs of development. Finally, they may be quickly rendered obsolete by changing consumer preferences or the arrival of competing products with new technologies or features.

*Interim, "topline", and preliminary data from its clinical trials that the Company announces or publishes from time to time may change as more patient data become available and are subject to confirmation, regulatory audit, and verification procedures that could result in material changes in the final data.*

From time to time, ONWARD may publicly disclose preliminary, interim, or "topline" data from our preclinical studies and clinical trials, based on a preliminary analysis of the data available at the time. Preliminary results are subject to change and should be viewed with caution. They may differ from future results of the same studies, or they may be qualified with different conclusions or considerations once the final data has been fully evaluated. That is because clinical outcomes may materially change as continued patient enrolment and treatment makes more patient data available, or as clinical trial participants continue other treatments for their disease. Differences between preliminary or interim data and

final data could significantly harm our business prospects. In addition, disclosure of interim data by ONWARD or our competitors could result in volatility in our share price.

If the preliminary, interim, or topline data that we report differ from actual results, or if third parties, including regulatory authorities, disagree with the conclusions reached, this could adversely affect our ability to obtain approval for and commercialize our investigational devices, and could harm our business, operating results, prospects, or financial condition.

*The Company's operations and reputation may be impaired if its information technology systems fail to perform adequately or if it is the subject of a data breach or cyber-attack.*

Our information technology (IT) systems are essential to the business' successful operation. We seek to allocate and manage the necessary resources to build, maintain, and protect our IT systems and infrastructure, as well as oversee third-party service providers. Any failure of our IT systems to perform as anticipated could disrupt our operations and result in transaction or reporting errors that could harm our business.

Our IT systems may be vulnerable to cyber-attacks or other security incidents, service disruptions, or other system or process failures. Such incidents could result in unauthorized access to vendor, consumer, or other types of confidential data, as well as disruptions to operations. While we have experienced such incidents in the past, none has been material to date.

We rely on third-party vendors for some of our IT processes and data management needs, which makes our operations vulnerable to a failure by any one of these vendors to perform adequately or to maintain effective internal controls.

To address these risks, we maintain an information security program that includes updating technology, developing security policies and procedures, implementing and assessing the effectiveness of controls, conducting risk assessments of third-party service providers, and adopting business processes designed to mitigate the risk of security breaches. However, there can be no assurance that these measures will prevent or limit the negative impact of a future incident on our operations or business reputation.

*A pandemic, epidemic, or outbreak of an infectious disease in Europe, the U.S., or worldwide, including the outbreak of the novel strain of coronavirus disease (COVID-19), could adversely affect its business.*

In 2021, the Company's business, financial condition, and results of operations were negatively affected by COVID-19 pandemic and the various restrictions and measures imposed by national, state, and local authorities in an effort to control the spread of the disease. Among others, research and development of our ARC$^{IM}$ System was impacted by work-from-home requirements, limiting our ability to test and debug hardware and software systems, as these processes require access to laboratories and equipment. We experienced delays in patient enrollment in our Up-LIFT Study from September 2020 to January 2021, and reduced productivity as a result of employees' inability to work due to illness.

A future wide-scale outbreak of infectious disease similar to COVID-19 could negatively affect our business in numerous ways. Our sales representatives, clinical specialists, and other personnel may be unable to travel and access customers for training and case support. Our production schedule may be affected if suppliers cannot manufacture or deliver parts and components on time. Pandemic-related restrictions could lead to, among others, inventory shortages or obsolescence; delays in approval of our devices by regulatory authorities; delays in decisions by insurance companies regarding coverage of our products; delays in clinical trials; delays in growing our sales organization; adjustments or disruptions to the business of third parties we work with, including suppliers, medical institutions, and clinical investigators; decrease in collectability of our account receivables due to the adverse impact of the pandemic on our clients' cash flows; and reduced capacity of our suppliers to advance our investigational devices through clinical trials.

While it is difficult to predict the potential economic impact and duration of a future outbreak, the current pandemic has resulted in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction could have an adverse effect on our long-term business as hospitals reduce capital spending.

To the extent that a pandemic (like COVID-19) adversely affects our business and financial results, it may also heighten many other risks described in this section, including those relating to incurring future operating losses, advance of the ARC$^{EX}$ and ARC$^{IM}$ platforms through regulatory pathways, and, if cleared or approved, successful commercialization, supply chain, and distribution channels.

*The Company's success depends on its ability to retain its management, consultants and other key personnel.*

ONWARD depends on its senior management as well as key scientific personnel. In 2020, Dave Marver was appointed as Chief Executive Officer. ONWARD's Chief Scientific Officer, Prof. Courtine, has been on the team since inception, in 2015, and currently serves as a consultant. The loss of any members of senior management or key scientific personnel could harm our business and significantly delay or prevent the achievement of research, development, or business objectives.

Our future success also depends on our ability to attract, hire, train, and retain other highly skilled scientific, technical, marketing, managerial, and financial personnel, as well as sales personnel once commercialization begins. Although we will make every effort to hire and retain qualified employees whose experience and abilities meet our needs, there is no assurance that we will succeed. Competition for personnel in the medical technology industry is intense, and any failure to attract and retain the necessary personnel would have a material adverse effect on our business.

**Risks Related to Government Regulation**

*The Company may not receive the necessary approvals, granted De Novo classifications, or clearances for its ARC$^{EX}$ and ARC$^{IM}$ platforms or future devices and expanded indications. Failure to obtain these regulatory clearances or approvals on a timely basis would adversely affect its ability to grow its business.*

ONWARD is seeking De Novo classification by the FDA to market ARC$^{EX}$ for use in clinics in the U.S. If this is granted, we intend to pursue additional regulatory clearances, including for at-home use. ARC$^{IM}$ is a Class III device that will require PMA approval to be marketed in the U.S., while for at least one indication, it may pursue HDE approval. In Europe, under the MDR, ARC$^{EX}$ is expected to be designated as a Class IIa device and ARC$^{IM}$ as Class III.

The road to regulatory approval of a new medical device is long, expensive, and uncertain. The FDA and other regulatory authorities can delay, limit, or deny approval, grant of a De Novo classification, or clearance of a device for many reasons, including:

- Inability to show that the products are safe or effective for their intended uses (or, for a 510(k) device, that they are substantially equivalent to the predicate)
- Disagreement with the design or implementation of clinical trials or the interpretation of data
- Serious and unexpected adverse device effects experienced by participants in clinical trials
- Insufficiently supportive data from preclinical studies and clinical trials
- Inability to show that the clinical and other benefits of the device outweigh the risks
- Manufacturing process or facilities used do not meet applicable requirements
- Changes in policies or regulations that increase cost of compliance or render clinical data and filings insufficient for approval or clearance

Despite the time, effort, and cost invested, our investigational devices may not pass these stringent regulatory hurdles, which could harm our business. In addition, regulatory authorities may place restrictions on the indicated uses of the device, limiting its market size. If the FDA requires us to go through a longer, more rigorous process than expected for future products, or for modifications to existing products, their introduction could be delayed or cancelled, which could adversely affect our ability to grow our business.

In the EEA, compliance with the requirements of the Council Directive 93/42/EEC (EU Medical Devices Directive) is a prerequisite to be able to affix the Conformité Européenne (CE) mark to our products, without which they cannot be sold or marketed in the EEA.

The EU Medical Devices Directive is being replaced by a new Medical Devices Regulation (MDR) in the EEA (Regulation (EU) 2017/745). The MDR, which became fully applicable on 26 May 2021, imposes the same basic requirements as the EU Medical Devices Directive (MDD), but is generally more stringent, especially in terms of risk classes and the oversight provided by notified bodies that perform conformity assessments of devices.

Following its departure from the EU on 31 January 2020, the UK continued to follow the same regulations as the EU during a transition period, which ended on 31 December 2020. Since then, all medical devices must be registered with the Medicines and Healthcare products Regulatory Agency (MHRA) before being sold on the UK market.

European CE marks will continue to be recognized in UK until 30 June 2023, after which a UK Conformity Assessed (UKCA) mark will be required for a medical device to be marketed in the UK. Since the new MDR will not automatically apply in the UK, regulation of medical devices in the UK may diverge from EU regulations in future. On November 28, 2022, the Swiss Parliament reached a key decision by instructing the Swiss Federal Council to adapt national laws to enable Switzerland to accept medical devices with FDA approval.

In general, If ONWARD fails to remain compliant with all applicable European laws and regulations, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EEA, adversely affecting our business. Similarly, our ability to market our products in the UK could be affected by any failure to maintain compliance with UK regulations.

*The clinical development process required to obtain regulatory clearances or approvals is lengthy and expensive, with uncertain outcomes. Data generated in clinical trials is subject to interpretation by EU regulators, the FDA, and foreign regulatory authorities. If clinical trials of the current ARC$^{EX}$ platform and ARC$^{IM}$ platform and future products do not produce the results necessary to support regulatory clearance or approval, De Novo classification, or clearance in the U.S. or -- with respect to the Company's current or future products — elsewhere, it will be unable to commercialize these products. It therefore may incur additional costs or experience delays in completing, or ultimately be unable to complete and commercialize those products.*

Significant setbacks or failure can occur at any time during the clinical development process, adversely affecting the cost, timing, or successful completion of trials. The following circumstances could harm our ability to complete development or commercialize our products:

- The FDA may reject our investigational device exemption (IDE) application and notify us that we may not begin investigational human clinical trials
- Regulatory authorities may disagree as to the design or implementation of our clinical trials
- Regulators and/or institutional review boards (IRBs) may not authorize us or our research partner to begin or continue a clinical trial at a particular site
- We may be unable to agree on acceptable terms with prospective contract research organizations (CRO) and clinical trial sites, the terms of which can vary significantly and require long negotiations
- Clinical trials may produce negative or inconclusive results, or we may not agree with regulatory authorities on the interpretation of these results; consequently, we may decide, or be required by regulators, to conduct additional clinical trials or abandon the development of a product
- The number of subjects or patients required for clinical trials may be larger than we anticipated, enrollment in these trials may be insufficient or slow, and/or the number of trials being conducted at any given time may be high, resulting in fewer available patients for our clinical trial, or patients may drop out at a higher than expected rate
- Our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all
- We may have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks
- We may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance

- We may be required to terminate clinical research for various reasons, including safety issues or non-compliance with regulatory requirements
- The cost of clinical trials may be greater than anticipated
- Clinical sites may not adhere to the clinical protocol or may drop out of a trial
- We may be unable to recruit a sufficient number of trial sites or trial subjects
- Regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes; the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate, or not available at an acceptable cost
- Approval policies or regulations may change in a manner that renders our clinical data insufficient for approval
- Our current or future products may have undesirable side effects or other unexpected characteristics

We depend on CROs to conduct clinical trials in a timely manner and in compliance with good clinical practice (GCP) requirements. If a CRO fails to comply fully with GCP standards or experiences delays in conducting the trial, this could result in increased costs and/or program delays. In addition, conducting clinical trials in countries outside the U.S. and Europe may entail additional delays, shipment costs, or regulatory requirements, as well as risks associated with clinical investigators who are unknown to the FDA, or with different standards of diagnosis, screening, and medical care. Any of these occurrences could adversely affect the Company's business, financial condition, and results of operations.

We may from time to time publicly announce the date at which we expect to reach various clinical, regulatory, or product development milestones. These could include the submission of an IDE application to the FDA to begin a clinical trial, the enrollment of patients in a trial, or the release of data from clinical trials. However, the actual timing of these milestones may vary dramatically compared to our estimates, in some cases for reasons beyond our control, potentially delaying the commercialization of our products or causing our share price to decline.

*Failure to comply with post-marketing regulatory requirements could subject the Company to enforcement actions, including substantial penalties, and might require the Company to recall or withdraw a product from the market.*

If we successfully secure FDA approval and clearance, our investigational devices will remain subject to oversight and regulation by the FDA throughout the manufacturing and commercialization processes. In particular, we and our suppliers or manufacturers will be required to comply with the FDA's Quality System Regulations (QSR), covering the way we conduct and document the design, testing, production, control, quality assurance, labelling, packaging, sterilization, storage, and shipping of our products.

The FDA audits compliance with the QSR and other regulatory requirements through periodic announced and unannounced inspections of manufacturing and other facilities. Failure to meet these QSR requirements could delay production and lead to fines, difficulties in obtaining regulatory clearances and approvals, withdrawal of PMAs that have already been granted, product recalls, and various enforcement actions or sanctions. Such compliance failures or sanctions could have a material adverse effect on our reputation, business, results of operations, and financial condition.

*Failure to comply with post-marketing regulatory requirements could subject the Company to enforcement actions, including substantial penalties, and might require the Company to recall or withdraw a product from the market.*

If we receive regulatory clearance or approval for our investigational devices, we will be subject to ongoing and pervasive regulatory requirements governing, among other things, their manufacture, marketing, labeling, packaging, advertising, medical device reporting, sale, promotion, registration, storage, distribution, and listing. For example, ONWARD must submit periodic reports to the FDA as a condition of PMA approval. These reports include safety and effectiveness information about the device after its approval. Failure to submit such reports or to do so in a timely manner could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

In addition, the PMA approval for ARC[IM] Therapy may be subject to several conditions of approval, including a post-market extended follow-up of the premarket study cohort. Any failure to comply with the conditions of approval could result in the withdrawal of PMA approval and the inability to continue to market the device. Adverse outcomes in these studies could also be grounds for withdrawal of approval of the PMA.

The regulations to which ONWARD is subject are complex, and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after the proper regulatory authorization to market a device has been obtained, we have ongoing responsibilities under FDA and EU regulations and applicable laws and regulations of other countries.

Any failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state, EU or national regulatory authorities. Sanctions could include warning letters, fines, injunctions, consent decrees or civil penalties; recalls, termination of distribution, administrative detention, or seizure of products; suspension of one or more clinical studies; customer notifications, repair, replacement or refunds; restriction, partial suspension or total shutdown of production; delays in or refusal to grant requests for future regulatory approvals of new products, uses, or modifications to existing products; withdrawals or suspensions of current regulatory approvals; prohibitions on sales, imports, or exports of our products; FDA refusal to issue certificates to foreign governments needed to export our products for sale in other countries; and criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition, and operating results.

*In the case that the Company obtains approval for its products, it may be subject to enforcement action if it engages in improper marketing or promotion of its products.*

ONWARD is not permitted to promote or market ARC[EX] and ARC[IM] so long as they remain investigational products. If approved, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, use. Surgeons may use our products off-label, as the FDA does not restrict or regulate a surgeon's choice of treatment within the practice of medicine. However, if the FDA determines that ONWARD's promotional materials or training methods constitutes promotion of an off-label use, it could request us to modify them or subject us to regulatory or enforcement actions. Other federal, state, or national enforcement authorities could also take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of our products could be impaired. In addition, the off-label use of our products may increase the risk of product liability claims, which are expensive to defend and could divert the attention of management, result in substantial damage awards, or harm our reputation.

*Even if cleared or approved by regulatory authorities, its products may cause or contribute to adverse medical events or be subject to failures or malfunctions that the Company is required to report to the FDA, and if it fails to do so, it would be subject to sanctions that could harm its reputation, business, financial condition and results of operations. The discovery of serious safety issues with its products, or a recall of its products, either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on the Company.*

In the event that we receive clearance or approval by regulatory authorities, we will be subject to the FDA's medical device reporting regulations and similar foreign regulations. This will require us to report to the FDA when we become aware of information that reasonably suggests that our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if it were to recur, could cause or contribute to a death or serious injury. The timing of this obligation to report is triggered by the date we become aware of the adverse event, as well as the nature of the event. ONWARD may inadvertently fail to report adverse events within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as such, or if the adverse event is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal

prosecution, civil monetary penalties, revocation of device approvals, seizure of our products, or delay in clearance or approval of modifications to our products.

The FDA and foreign regulatory authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall of our products must be based on a finding that there is reasonable probability that they may cause serious injury or death. ONWARD may also choose to voluntarily recall products if any material deficiency is found. A government-mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects, or other deficiencies or failures to comply with applicable regulations. Depending on the corrective action that we takes to redress deficiencies or defects that may occur in the future, the FDA may require, or we may decide, that we need to obtain new approvals for our products before marketing or distributing the corrected device. Seeking such approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we fail to adequately address problems associated with our products, we may face additional regulatory enforcement action.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. In the future, ONWARD may initiate voluntary withdrawals or corrections to our products that we may determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and subject us to enforcement action. Such a recall announcement could harm our reputation with customers, potentially lead to product liability claims, and negatively affect sales. Any lawsuit or corrective action, whether voluntary or involuntary, would require the dedication of considerable time and capital, possibly impacting our financial results.

Additionally, the identification of undesirable side effects or other previously unknown problems caused by our products could lead to a number of negative consequences. Among others, regulatory authorities might withdraw approvals; impose product recalls; require us to add warnings, contraindications, or narrower indications in the product labeling, or to issue of field alerts to physicians and pharmacies; require us to create a guide outlining the risks of such side effects for distribution to patients; impose limitations on how we promote our products; require us to change the way the product is administered or modify the product; and require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Any of these requirements could prevent us from achieving or maintaining market acceptance of our products, substantially increase the costs of commercializing our products, or impacts our sales. The demand for our products could also be negatively impacted by any adverse effects of a competitor's product or treatment.

**Risks Related to the Company's Intellectual Property**

*The Company licenses certain technology underlying the development of its investigational devices. Loss of a license would result in a material adverse effect on its business, financial position, and operating results and cause the market value of its Ordinary Shares to decline.*

ONWARD licenses technology from EPFL, UCLA, Caltech, University of Louisville, University of Minnesota, University of Calgary, and University of British Columbia that is integrated into our company portfolio under five licenses, each exclusive in the Company's Field of Uses. Under our different license agreements, the Company has agreed to milestone payments and/or to meet certain reporting obligations.

Were the Company to breach any obligations under these agreements, licensors would have the right to terminate the agreements. In addition, licensors have the right to terminate their respective licenses upon the bankruptcy or receivership of the Company.

If the Company is unable to continue to use or license this technology on reasonable terms, or if this technology fails to operate properly, we may not be able to secure alternatives, negatively affecting our ability to develop our products.

*It is difficult and costly to protect its IP and its proprietary technologies, and the Company may not be able to ensure their protection.*

We rely on a combination of patents and trade secrets to protect the IP related to our proprietary technologies. Patents and other proprietary rights provide uncertain

protections, and we may be unable to protect our IP for various reasons, including complex factual and legal issues that create uncertainty as to the validity, scope, and enforceability of a particular patent. As a result, we may be unsuccessful in defending our patents and other proprietary rights against third-party challenges, which could have a material adverse effect on our business.

Patents do not automatically provide a competitive advantage. Competitors may be able to design around our patents and develop products that provide comparable or superior outcomes. Any changes we make to our products, including design improvements that we believe make them more marketable, may not be covered by previously licensed patents. We may be required to file new applications and/or seek other forms of protection covering these alterations.

Changes in either patent laws or their interpretation in the U.S. and other countries may diminish our ability to stop third parties from making, using, selling, or importing products that infringe on our intellectual property. Infringement and/or misappropriation suits are expensive and time-consuming to prosecute, and could result in a court deciding that one or more of our patents is invalid, unenforceable, or both. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology on the grounds that their activities are not covered by the patents.

We may in future obtain certain IP related to our technology from third parties. If that is the case, we cannot be certain that these third parties took the necessary actions to maintain the IP rights or that their transfer to us was proper and effective. As a result, we may be subject to claims challenging their ownership or enforceability, which would limit our ability to prevent competitors from making or selling duplicate or similar technologies for which, or in countries where, we have no patent protection.

In addition to patents, we rely on trade secrets to protect our technology. We have established policies to protect our trade secrets, but these may not be effective in preventing misappropriation or unauthorized disclosure. Litigating a trade secret claim is expensive and time-consuming, and the outcome may be unexpected. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop knowledge and/or methods allowing them to create substantially similar products or services without misappropriating our trade secrets.

*Patent terms may be inadequate to protect the Company's competitive position on its future products for an adequate amount of time.*

In both the U.S. and Europe, a patent's lifespan is generally 20 years from its earliest filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering the Company's future products are obtained, once the patent has expired, it may be open to competition from competitive products.

ONWARD's current patent portfolio will begin to naturally expire in 2031. However, given the amount of time required for the development, testing, and regulatory review of new products, certain patents protecting our future products may expire before or shortly after commercialization begins. As a result, our patent portfolio may not provide the Company with sufficient rights to exclude others from commercializing similar or identical products for a sufficient amount of time.

*If the Company is unable to protect the confidentiality of its trade secrets, its business or competitive position could be harmed.*

To protect our confidential and proprietary information, we rely on non-patent protection such as trademark or trade secret protection and confidentiality agreements with employees, consultants, vendors, and third parties. We also implement commonly accepted physical and technological security measures to protect our confidential information.

However, these measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor. Unauthorized parties may also attempt to copy or reverse-engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be expensive and time-consuming, and the outcome is unpredictable. The criteria for protecting trade secrets can vary among different jurisdictions. Moreover, trade secrets may be independently developed by others in a way that could prevent legal recourse.

If any of our confidential or proprietary information were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed.

*The Company relies on licenses and sublicenses to certain patent rights with third parties. If the Company fails to comply with its obligations under its patent licenses with third parties, it could lose license rights that are important to its business. In addition, the Company may not be able to control the prosecution or maintenance of such patent rights, which could adversely affect its business.*

ONWARD relies on licenses and sublicenses to certain patent rights and other IP from third parties that are necessary for developing our products, including the software modules that we expect to integrate into our ARC$^{EX}$ and ARC$^{IM}$ platforms. All of the following circumstances related to licensing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects:

- Future licenses we enter into may not provide exclusive rights to use the related IP for all fields of use or territories in which we wish to develop or commercialize our products; we therefore would not be able to prevent other companies from developing or marketing competing products
- As some of the underlying IP rights related to a license would not belong to us, our rights would be subject to the continuation and compliance with the terms of the licensing agreement; if the agreement were terminated, competitors would have the freedom to develop and market products similar or identical to ours
- If our licensor concludes that we have materially breached the license agreement and terminates it, we may have to cease developing, manufacturing, or marketing any product covered by these agreements
- A license agreement may not grant us the right to control the preparation, filing, prosecution, or maintenance of patents and patent applications covering our products; if our licensing partner fails to adequately manage these rights, we may be unable to prevent competitors from developing or commercializing similar or identical products
- Where we have the right to control the prosecution and maintenance of relevant patents, we may still be adversely affected by actions that took place prior to the date in which we assumed control
- Where we are permitted to pursue the enforcement or defense of these patents, we cannot be certain that the licensors will provide us with the necessary cooperation, or that they will allocate sufficient resources to defend their interests; an adverse outcome from any legal action, even if we are not a party to it, could harm our business by preventing us from continuing to license IP we need to operate our business
- If other third parties, in addition to the licensor, have ownership rights to these patents, they may be able to license them to our competitors; we may need to obtain additional rights from them or we could be prevented from developing and commercializing the related products
- If we need to amend existing licenses, the licensor may impose terms that are more favorable to them, including terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the related IP

*The Company may be required to pay certain milestones and/or royalties and fulfil other obligations under its license agreements with third-party licensors.*

ONWARD may be required to pay milestones and/or royalties related to the development or commercialization of products using technologies that we may license or sublicense from third parties. These payments could adversely affect our profitability related to products that we may seek to develop or commercialize in future.

We may need to meet specified milestones or fulfill certain obligations to maintain these licensing agreements, such as devoting a certain quantity of resources to developing our products. Failure to satisfy such obligations could result in the termination of our rights under such agreements.

*The Company may in the future become involved in lawsuits to defend itself against intellectual property disputes, which could be expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, and*

*hinder its ability to commercialize its existing or future products.*

ONWARD's success depends in part on not infringing the patents or violating the other proprietary rights of others. Significant litigation regarding patent rights occurs in the medical industry. Intellectual property disputes can be costly to defend and may cause our business, operating results and financial condition to suffer.

Whether merited or not, it is possible that US and foreign patents and pending patent applications controlled by third parties may be alleged to cover ONWARD's products. Determining whether a product infringes a patent, as well as priority of inventions and other patent-related disputes, involves complex legal and factual issues and the outcome is often uncertain. While we have conducted a significant search of patents issued to third parties, this is not a guarantee that we will not face intellectual property suits in relation to our patent portfolio.

Additionally, third-party patents containing claims covering our technology or methods that predate our patents may exist. Because of the number of patents issued and patent applications filed in the fields related to our products, our competitors or other third parties may assert that our technology and the methods employed in the use of products incorporating our technology are covered by patents they hold. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending, or published but not yet granted, of which we are unaware.

As the number of competitors in the medical devices market increases, and as the number of patents issued in this area grows, the possibility of infringement claims against ONWARD increases. Defending against such litigation is costly and time consuming, and the uncertainties resulting from litigation could negatively affect our ability to raise the funds necessary to continue to operate. Moreover, any potential patent or intellectual property litigation could force ONWARD to do one or more of the following:

- stop selling, making, using, or exporting products that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, making, exporting, or using products, which may require substantial royalty payments and may not be available on reasonable terms;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights it may be found to be infringing;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products and services;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to infringe;
- find non-infringing substitute products, which could be costly and create significant delay due to the need for prior FDA authorization;
- find alternative supplies for infringing products or processes, which could be costly and create significant delay due to the need for FDA regulatory clearance or approval; and/or
- redesign those products or processes that infringe any third-party intellectual property, which could be costly, disruptive, and/or infeasible.

If any of these consequences occur, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, which could have a material adverse effect on our business, as we are currently only pursuing regulatory approval in certain indications for two investigational devices, ARC$^{EX}$ and ARC$^{IM}$. We could also be required to indemnify customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our products.

Similarly, interference or derivation proceedings provoked by third parties or brought by the United States Patent and Trademark Office or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship

with respect to ONWARD's patents or patent applications. An unfavorable outcome in such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all.

Lastly, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of ONWARD's confidential information could be compromised by disclosure during discovery. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the price of the Ordinary Shares. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of the Ordinary Shares.

**Risks Related to the Company's Financial Position, Need for Additional Capital, and Taxation**

*The Company has incurred significant operating losses since inception, expects to incur operating losses in future, and it may not be able to achieve or sustain profitability.*

ONWARD is a medical technology company with no commercial operating history. To date, we have substantially invested all of our efforts in the research and development of, and in seeking regulatory clearance or approval for, our ARC$^{EX}$ and ARC$^{IM}$ platforms. We are not profitable, have incurred losses each year since beginning operations in 2014, and have no commercial operating history upon which to evaluate our business and prospects. Any predictions of future success, performance, or viability may not be as accurate as they could be if the Company had a longer operating history or commercial revenues.

ONWARD has not yet derived sufficient revenues to support operations, as our activities have consisted of developing our technology and conducting preclinical studies and clinical trials. As of 31 December 2022, the loss brought forward amounted to EUR 108M. These losses have resulted primarily from costs incurred in the development of the ARC$^{EX}$ and ARC$^{IM}$ platforms, and from general and administrative costs associated with operations.

The current or future clinical trials of any current or future investigational devices are, and the manufacturing and marketing of any such investigational devices will be, subject to extensive and rigorous review and regulation by the FDA and other government authorities in the U.S. and in other countries where the Company intends to test and, if cleared or approved, market such investigational devices. We expect our operating expenses to continue to increase as we

(i) continue research and development activities for our ARC$^{EX}$ and ARC$^{IM}$ technology platforms and related technologies;

(ii) seek FDA regulatory clearances and approvals for the ARC$^{EX}$ and ARC$^{IM}$ platforms or other future investigational devices in the U.S., regulatory approvals in Europe, and potentially other regulatory approvals in other jurisdictions;

(iii) build our commercial infrastructure; and

(iv) incur additional operational costs associated with being a public company.

As a result, ONWARD expects to continue to incur operating losses for the foreseeable future. The expected future operating losses, combined with prior operating losses, may adversely affect the market price of our Ordinary Shares and our ability to raise capital and continue operations.

We expect sales of our ARC$^{EX}$ and ARC$^{IM}$ platforms, if cleared or approved, to account for the majority of our future revenue. If the ARC$^{IM}$ and/or ARC$^{EX}$ platforms do not achieve regulatory clearance or approval or if the platforms do not generate sufficient revenue, the Company may not be able to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability in subsequent periods or on an ongoing basis. In this case, it will be more difficult for us to finance our business and realize our strategic objectives, which would have a material and adverse effect on our business, financial condition, and results of operations and would cause the market price of our Ordinary Shares to decline.

*The Company will require additional capital to finance its planned operations, which may not be available to it on acceptable terms or at all.*

As of 31 December 2022, ONWARD had net cash of EUR 62M. Based on cash-flow forecasts for 2023 and 2024, we believe this will be sufficient to meet our capital requirements and fund our operations for at least 12 months as of the date of this Annual Report. However, we have based these estimates on assumptions that may prove to be incorrect and could spend our available financial resources much faster than currently expected.

The Company's expenses will also increase substantially in connection with any potential commercialization of our products in the U.S. and Europe, including the hiring of qualified and sales personnel. Additional expenditures will include costs associated with manufacturing and supply, expenses related to the deployment of a direct sales and service organization, costs and expenses incidental to being a public company, and general operations. In addition, other unanticipated costs may arise.

The Company's present and future funding requirements will depend on many factors, including:

- Continuing our research and development efforts, completing ongoing and planned clinical trials, and applying for (i) De Novo classification granting marketing authorization for ARC$^{EX}$ for use in clinics, and thereafter 510(k) clearance for use of ARC$^{EX}$ in the home, and (ii) PMA approval, which will be required for ARC$^{IM}$, though we expect to pursue approval to legally market at least one indication via HDE
- Conducting additional clinical trials of our ARC$^{EX}$ and ARC$^{IM}$ platforms for future indications
- Our ability to retain and compensate the highly qualified personnel necessary to execute our plans
- If cleared or approved, the costs associated with manufacturing, selling, and marketing our products in Europe and the U.S., as well as other foreign jurisdictions, including the cost and timing of implementing our sales and marketing plan and expanding manufacturing capabilities
- Our ability to effectively market and sell, and achieve sufficient market acceptance and market share for, our products
- The costs to maintain, expand, and defend the scope of our intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other IP rights
- The emergence of competing technologies and other adverse market developments, and the need to enhance our products and/or develop new products to maintain market share
- Our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements
- Our need to implement additional internal systems and infrastructure, including financial and reporting systems, incidental to being a public company

The Company will likely need to raise additional capital. If we do so through public or private equity offerings, the ownership interest of existing shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect these shareholders' rights. If the Company raises additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or liens, making capital expenditures, or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our ARC$^{EX}$ and ARC$^{IM}$ platforms, technologies, future revenue streams, or research programs, or grant licenses on terms that may not be favorable to us.

If we are unable to obtain adequate financing when needed, and on terms that are acceptable to us, we may have to delay, reduce the scope of, or suspend the implementation of our sales and marketing plan and our ongoing research and development efforts, which would have a material adverse effect on our business, financial condition, and results of operations.

*The Company's operating results may vary significantly from period to period, which may negatively impact the price of its Ordinary Shares in the future.*

ONWARD's financial and operating results may fluctuate from period to period due to, among others:

- The cost of obtaining and maintaining FDA and other regulatory clearances or approvals for our ARC$^{EX}$ and ARC$^{IM}$ platforms, as well as any other future indication we may seek to develop our investigational devices to address
- Potential revenue generated by sales of our ARC$^{EX}$ and ARC$^{IM}$ platforms for cleared or approved indications, if any
- Expenses incurred in manufacturing and selling our ARC$^{EX}$ and ARC$^{IM}$ platforms, if cleared or approved
- Costs associated with scaling up and expanding our manufacturing capacity
- Costs associated with building and expanding our sales and marketing efforts in the U.S., Europe, and internationally
- Costs associated with conducting research and development efforts for future improvements to, or versions of, our ARC$^{EX}$ and ARC$^{IM}$ platforms
- Cost of complying with regulatory requirements
- Costs associated with capital expenditures
- Costs associated with any future litigation
- Costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our IP rights, and defending any IP-related claims
- The severity, duration, and impact of a pandemic (like COVID 19), which may adversely impact our business and planned development and future commercialization of our ARC$^{EX}$ and ARC$^{IM}$ platforms

Due to these and other factors, it is likely that ONWARD will experience fluctuating revenues, operating results, and cash flows. In that case, period-to-period comparisons of financial results may not necessarily be meaningful, and results of operations in prior periods should not be relied upon as an indication of future performance as this will not meet investor expectations or those of public market analysts. Unanticipated or new information may cause investors and analysts to revalue our business, which could cause a decline in the price of our Ordinary Shares.

The Company's ability to use its net operating losses and research and development credit carryforwards to offset future taxable income may be subject to certain U.S. federal income tax and Dutch tax limitations.

In general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change" — generally defined as a greater than 50% change by value in its equity ownership over a three-year period — is subject to limitations on its ability to use its pre-change net operating losses (NOL) and its research and development credit carryforwards to offset future taxable income. The Company's existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if it undergoes an ownership change, our ability to use NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Internal Revenue Code.

In addition, our ability to deduct net interest expense may be limited if the Company has insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. Future changes in share ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Internal Revenue Code.

For these reasons, in the event that ONWARD experiences a change of control, we may not be able to use a material portion of the NOLs, research and development credit carryforwards, or disallowed interest expense carryovers, even if we attain profitability.

# Investor Relations

We engage in and maintain open dialogue with investors and analysts through several communication channels, including the Annual General Meeting, roadshows, investor conferences, presentations, and webcasts.

Up-to-date financial information about ONWARD is published on our Investor Relations website **(ir.onwd.com)**. Investors and analysts are encouraged to visit the website regularly for detailed coverage of the share price, shareholder meetings, half-year and annual results, press releases, presentations, webcasts, and investor relations events.

**Financial Calendar 2023**

- 27 March: Annual Report publication
- 8 May: Annual General Meeting
- 12 September: Interim Report publication

During a closed period before publication of the Company's annual and half-year results, we do not engage in discussion with analysts, investors, or financial journalists or make presentations at investor conferences.

Closed periods based on the 2023 financial calendar are:

- 26 February – 27 March 2023
- 14 August – 12 September 2023

**Dividend Policy**

ONWARD has not declared or paid dividends on its shares in the past and does not currently have the intention to pay dividends. Any declaration of dividends will be based on the Company's earnings, financial condition, capital requirements, and other factors considered important by the Board.

Dutch law and ONWARD's Articles of Association do not require the Company to declare dividends. Currently, the Board expects to retain all earnings, if any, generated by ONWARD's operations for the development and growth of the business and does not anticipate paying dividends to shareholders in the near future.

Under the terms of the Innovation loan received from the RVO NL (Dutch Government), ONWARD is not allowed to pay dividends until the Innovation loan has been repaid.

**Capital Structure & Voting Rights**

The authorized share capital of ONWARD comprises 50,937,500 Ordinary Shares and 50,937,500 Preferred Shares. At 31 December 2022, 30,184,188 issued Ordinary Shares are fully paid-up and represent capital in the Company. There are no convertible securities, exchangeable securities, or securities with warrants in the Company. No shareholders have any voting rights different from any other shareholder, and no voting rights are limited in any manner.

ONWARD is not aware of any agreements that may result in a limitation of the transferability of voting rights on shares in its capital.

## Shareholder Structure

Pursuant to the Dutch Financial Supervision Act (Wet op het financieel toezicht), substantial holdings in the Company must be disclosed to the Netherlands Authority for Financial Markets (Stichting Autoriteit Financiële Markten, AFM). According to the register kept by the AFM, the following shareholders disclosed that they have a direct or indirect (potential) interest of between 3% and 25% in the Company's total issued share capital as of 31 December 2022:

- NRT Holdings LLC (12.15%)
- INKEF Capital B.V. (12.11%)
- LSP Advisory B.V. (11.33%)
- Gimv (Private Equity) (10.61%)
- Wellington Partners GmbH (8.74%)
- Invest-NL N.V. (3.6%)
- Dave Marver (CEO) (3.16%)

## Listing

Shares of ONWARD Medical N.V. trade on Euronext in Brussels (primary listing) and Euronext Amsterdam (secondary listing) under the symbol "ONWD."

## Share Price


## Analyst Coverage

ONWARD was covered by three brokers at the end of 2022.

| Broker | Analysts |
|---|---|
| **Degroof Petercam** | David Seynnaeve, PhD |
| **Kepler Cheuvreux** | Jon Berggren |
| **Bryan, Garnier & Co** | Alex Cogut |

# Report of the Non-Executive Directors

Below is the report of the Non-Executive Directors of the Company for the financial year 2022, as referred to in Best Practice Provision 5.1.5 of the Corporate Governance Code (CGC).

**Supervision by the Non-Executive Directors**

The Non-Executive Directors supervise the policies implemented by the Executive Director and Management Team, and the general affairs of the Company and its affiliated entities, including the deployment of the Company's strategy regarding long-term value creation.

With a view to maintaining supervision of the Company, the Non-Executive Directors regularly discussed strategic matters with the Executive Director and Management Team during Board meetings, such as annual financial reports, financial transactions, the annual budget, and long-term business plans.

In addition, the Non-Executive Directors have examined and monitored each and all stages of the domiciliation process and have taken all relevant decisions.

The Board has allocated certain specific responsibilities to the Audit Committee, Compensation Committee, and Nomination and Corporate Governance Committee. Further details on how these Committees have carried out their duties are set forth in the sections below pertaining to each committee. The Non-Executive Directors have been regularly informed by each committee of the results and recommendations of these meetings in accordance with Best Practice Provision 2.3.5 of the CGC, and the conclusions of those committees were considered when drafting this report of the Non-Executive Directors.

**Audit Committee**

The main topics discussed by the Committee in 2022 were as follows:

- The operation of the internal risk-management and control systems, including supervising the enforcement of the relevant legislation and regulations and supervising the operation of ONWARD's Code of Conduct
- The provision of financial information by the Company (including, but not limited to, the choice of accounting policies, applying and assessing the effects of new rules, information about the treatment of estimated items in the financial statements, forecasts and external auditors)
- Relations with the external auditor, including the audit plan and the external auditor's independence (also considering any non-audit services provided) and remuneration
- The financing of the Company
- The need for an internal audit function
- Various updates on the application of information and communication technology, including cybersecurity matters

In relation to the above topics, the Committee made recommendations and issued advice to the Board for approval (where applicable). In 2022, the Audit Committee held six meetings in total (attendance details provided in the table below).

### Compensation Committee

The main activities carried out by the Compensation Committee during 2022 were as follows:

- Submitting proposals to the Board concerning changes to the Company's compensation policy
- Submitting proposals to the Board concerning the compensation of individual Directors and the Management Team, including the compensation structure, amount of fixed and variable compensation components, and pay ratios within the group
- Approving the proposal to grant stock options to the Management Team`
- Approving adjustments to executive compensation (salary and stock options) following the annual review of executive compensation performed by an external consultant
- Evaluating a preliminary proposal of the employee stock ownership plan (reserved for non-Director employees)
- Preparing the Company's compensation report

In relation to the above topics, the Committee made recommendations and issued advice to the Board for approval (where applicable). In 2022, the Compensation Committee held three meetings in total (attendance details provided in the table below).

### Nomination & Corporate Governance Committee

The main activities carried out by the Nomination and Corporate Governance Committee during 2022 were as follows:

- Establishing selection criteria and appointment procedures for Directors
- Reviewing the size and composition of the Board and submitting proposals for the composition profile of the Board (where required)
- Reviewing the functioning of individual Directors and reporting on the results of this review to the Board
- Submitting proposals for (re)appointment of Directors
- Supervising the Board's policy regarding selection criteria and appointment procedures for the Company's senior management and executive officers
- Examining the corporate governance report pursuant to applicable law

In relation to the above topics, the Committee made recommendations and issued advice to the Board for approval (where applicable). In 2022, the Nomination and Corporate Governance Committee held two meetings in total (attendance details provided in the table below).

The Non-Executive Directors also examined the report prepared by the Compensation Committee and subsequently approved by the Board. The Non-Executive Directors were able to review and evaluate the performance of the Nomination and Corporate Governance Committee. There is no need to amend the size or composition of any of the above committees.

## Evaluation

The Board is responsible for the quality of its own performance. Once per year, it discusses its own performance and the performance of its individual members and committees.

In addition, the Non-Executive Directors evaluated their own performance via a self-assessment in 2022. The self-assessment was based on a detailed questionnaire completed by all Non-Executive Directors. The feedback from individual Directors was summarized, subsequently evaluated, and discussed in the December 2022 Board meeting.

The questionnaire gave attention, in particular, to timely and accurate sharing of information, the functioning of the committees, functioning and performance of the entire Board, interaction with the Executive Director and Management Team, Board accountability, and standards of conduct. The Non-Executive Directors concluded that they are operating well, with all members participating in open discussions and contributing constructively. It assessed individual members' expertise and whether their combined expertise is in line with the Company's characteristics and business. Several suggestions for further improvement were made. These included a desire to spend more time discussing strategic matters among Board members, timely information sharing between Board committees and the full Board, and the evolution of Board dynamics since transitioning to a public company.

For 2022, the Board's performance evaluation resulted in a positive assessment of the Board and its individual members.

## Internal Audit Function

As per the Audit Committee's recommendation, the Board concluded that — due to the size of the Company — it does not yet require an internal audit function. The Board has assessed whether adequate alternative measures have been taken, and will reconsider annually if it is necessary to create an internal audit department.

In reaching this conclusion, the Board took into consideration that the Company has provided for management to support the assessment and testing of our risk-management and control systems.

## Independence of the Non-Executive Directors

Each Non-Executive Director has a duty to the Company to properly perform the duties assigned to them and to act in the Company's corporate interest. Under Dutch law, the Company's corporate interest extends to the interests of all stakeholders, including shareholders, creditors, and employees.

The Board confirms that the Non-Executive Directors meet the independence requirements of the CGC. For details refer to Director Independence included in the Governance section.

2022

# Meetings of the Board & Committees

| | | Board of Directors | Audit Committee | | Compensation Committee | | Nomination & Corporate Governance Committee | |
|---|---|---|---|---|---|---|---|---|
| **Member & Principal Position** | **Independent According to DCGC** | **% of Attendance at Meetings** | **Member** | **Attendance % at Meetings** | **Member** | **Attendance % at Meetings** | **Member** | **Attendance % at Meetings** |
| **Dave Marver** Executive Director & CEO | No | 100% | | | | | | |
| **Jan Ørhstrøm** Non-Executive Director & Chairperson | Yes | 100% | | | Xa | 100% | Xa | 100% |
| **Grégoire Courtine** Non-Executive Director and CSO | No | 100% | | | | | | |
| **Ian Curtis** Non-Executive Director and Vice-Chairperson | Yes | 100% | Xa | 100% | | | | |
| **Fredericus Colen** Non-Executive Director | Yes | 100% | X | 100% | X | 100% | | |
| **Regina Hodits** Non-Executive Director | No | 100% | | | | | X | 100% |
| **John de Koning** Non-Executive Director | No | 100% | | | | | X | 100% |
| **Kristina Dziekan**[b] Non-Executive Director | Yes | 100% | X | 100% | | | | |
| **Vivian Riefberg**[c] Non-Executive Director | Yes | 100% | | | X | 100% | | |
| **Number of Meetings Held:** | | 7 | | 6 | | 3 | | 2 |

*a: Chairperson of the respective committee.*
*b: Kristina has attended all Board meetings since her appointment on 10 June 2022, and all Audit Committee meetings since her appointment on 26 September 2022.*
*c: As Interim Director (expected to be nominated for appointment as Director at our 2023 Annual General Meeting), Vivian has attended all Board and Compensation Committee meetings since 26 September 2022.*

# Board of Directors' Statements

The Board of Directors' Report (the Report), consisting of pages 4-171 inclusive and such parts of the financial statements as referred to in the Report, comprise the Bestuursverslag, as defined in Article 2:391 of the Dutch Civil Code (DCC).

In accordance with Best Practice Provision 1.4.3 of the Dutch Corporate Governance Code (CGC), and with reference to the risk-management and control section on pages 133-167 and the financial review on pages 102-107 of this Annual Report, the Board of Directors confirms that, to the best of its knowledge:

- The Report provides sufficient insights on any deficiencies in the effectiveness of the Company's internal risk and control systems; no deficiencies in the effectiveness of the internal risk and control systems have been identified
- The Company's internal risk-management and control systems provide reasonable assurance that our financial reporting does not contain any material inaccuracies
- There is reasonable expectation that the Company will be able to continue operations and meet its liabilities for at least 12 months; therefore, it is appropriate to adopt the going concern basis in preparing the financial reporting, as referred to in Note 1.4 of the Consolidated Financial Statements
- There are no material risks or uncertainties that could reasonably be expected to have a material adverse effect on the continuity of the Company's operations in the coming 12 months

With reference to Section 5.25c, Paragraph 2c of the Financial Markets Supervision Act, the Board states that, to the best of its knowledge:

- The consolidated financial statements as at and for the year ended 31 December 2021 — which have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union and with Part 9 of Book 2 of the DCC — give a true and fair view of the assets, liabilities, financial position, and loss of the Company and the undertakings included in the consolidation taken as a whole
- The Report provides a fair view of the situation on the balance sheet date and of developments during the financial year of the issuer and of its affiliated companies, whose information has been included in its financial statements, together with a description of the main risks the issuer faces

Amsterdam, 27 March 2023 – **Board of Directors**

# Remuneration Report

This report provides an overview of the remuneration of the Board in 2022 and explains how this relates to the Company's policy regarding the remuneration of its Non-Executive and Executive Directors (the Compensation Policy), which was previously adopted at the Company's 2021 Annual General Meeting (AGM). The adoption of the 2021 report was through an advisory vote with 87.75% of voting in favor of adoption.

The 2022 Remuneration Report has been prepared in line with Section 2:135b of the Dutch Civil Code (DCC) and Best Practice Provision 3.4.1 of the Corporate Governance Code (CGC). This report will be submitted to the 2023 AGM for an advisory vote. The Company's 2023 AGM is scheduled for 15 June.

The Compensation Policy is available on the ONWARD website **(onwd.com)** under Investors/Governance tab.

### Executive Director Remuneration

The annual remuneration of the Executive Director comprises the following two components:

- Fixed remuneration, comprising an annual base salary and optional benefits, such as medical insurance, life insurance, retirement benefits, travel expenses, and/or representation allowances
- Variable remuneration, comprising an annual performance-based compensation (depending on the individual's achievement and corporate objectives as defined on an annual basis) and share-based remuneration

### Fixed Remuneration

The amount of the fixed remuneration depends on the Executive Director's function and responsibilities and on typical compensation levels in the industry and the market, especially in comparison to similar listed companies in the MedTech sector. The fixed remuneration is paid out as a monthly salary.

### Variable Remuneration

Short-term variable remuneration consists of annual performance-based compensation (a bonus) defined on a yearly basis. The company considers both corporate and individual objectives. Corporate objectives are centered around strategic R&D deliverables, key regulatory milestones, and financing goals. These objectives are measured via a set of specific targets that help track progress towards their completion.

Long-term variable remuneration consists of periodic grants of stock options that vest monthly over a four-year vesting period. For more details refer to Note 2.9 In the Consolidated Financial Statements. Stock options create an ownership opportunity for executives linked to the long-term performance of the Company's share price, aligning their interests with those of shareholders over the options' 10-year term. If the share price does not increase from the date of grant, no value is realized under the scheme.

Stock options are commonly leveraged as the primary equity vehicle among our industry peer group in Europe and the U.S. Award sizes are determined at the point of grant in relation to competitive award values and percentage of ownership delivered within our peer group.

The Company has implemented share-based remuneration as follows:

- Share-based remuneration takes the form of options for shares
- These options may not be transferred, pledged, or otherwise encumbered; subject to, among others, the applicable yearly exercise periods, they may be exercised for up to 10 years after the grant date once vested
- In cases of termination of an Executive Director's management agreement (other than termination by the Executive Director for good cause) who holds share options, or if that Executive Director is dismissed, such options are subject to reverse vesting (and as such will be forfeited) over a period of 36 months after their grant
- This plan is not based on the achievement of specific performance-related Key Performance Indicators (KPI's); however, the size of the stock option grant is linked to the position's job grade and is contingent on an individual's performance in the previous calendar year
- The plan is based on the premise that stock options contain an inherent performance criterion for the recipient, who is invested in the successful performance of the Company, thereby leading to an increase in the share price

There are no specific performance conditions associated with this plan, only a service condition. This deviates from the requirements of Best Practice Provision 3.1.2 v of the CGC. In addition, refer to the section "Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code" of the Governance section for further information.

An award letter was granted to the Company's Executive Director in December 2021. The main conditions for exercising these options are described above. No award was granted to the Executive Director in 2022.

| Executive Director | Financial Year | Grant Date | Type of Security | Options Vested / Unvested | Exercise Price | Expiration Date |
|---|---|---|---|---|---|---|
| **Dave Marver** | 2021 | 15/12/2021 | Stock Options | Vested: 49,089 Unvested: 138,911 | EUR 9.70 | 15/12/2031 |

### Reduction or Claw-Back of Variable Remuneration

Pursuant to Dutch law, the variable remuneration of the Executive Director may be reduced, or the Executive Directors may be obliged to pay part of their variable remuneration to the Company, if certain circumstances apply as follows:

- Test of reasonableness and fairness: According to Dutch law, the Board may adjust any variable remuneration payable to an Executive Director to an appropriate level if payment of the variable remuneration is deemed unacceptable according to the criteria of reasonableness and fairness
- Claw-back: Under Dutch law, the Board has the authority to recover from an Executive Director any variable remuneration paid based on incorrect financial or other data

### Contribution to Long-Term Performance & Value Creation

Remuneration of the Executive Director is consistent with and supports ONWARD's strategy. It also supports our ongoing efforts to improve our overall performance, facilitate growth and sustainable success, and enhance our long-term value and interests.

As a result, our compensation packages are designed to enable us to compete in a global market, including the challenging U.S. labor market. This approach enables us to attract both the required top talent to execute our long-term strategy and the necessary non-executive expertise to effectively supervise its execution, with the purpose of creating long-term value and sustainable growth in the best interest of the Company and our stakeholders.

### Executive Director's Remuneration in 2022

A detailed breakdown of the Executive Director's remuneration is presented in the table below:

| EUR'000 | Dave Marver CEO since 1 July 2020 | |
|---|---|---|
| | 2022 | 2021 |
| Base Salary | 410[b] | 340 |
| Pension Benefits | 44 | 28 |
| Relocation & Other Benefits | 109 | 228 |
| **Total Fixed Compensation** | 563 | 596 |
| Annual Performance-Based Compensation | 398 | 595 |
| Share-Based Remuneration / Stock Options | 469 | 2,140[a] |
| **Total Variable Compensation** | 867 | 2,735 |
| **Total Compensation** | 1,430 | 3,331 |

*a: Share-based remuneration relates to the Employee Investment Plan (EIP) vesting on the date of the IPO (EUR 2,118,495). The expense relating to stock options granted on 15 December 2021 amounted to EUR 21,289.*
*b: The increase in the base salary was to align the salary of the CEO with ONWARD's peer group based on benchmarking performed by an external consultant.*

### Scenario Analyses

No scenario analysis was taken into consideration in determining the Executive Director's remuneration for 2022. This deviates from the requirements of Best Practice Provision 3.4.1iii of the CGC.

Please refer to the section "Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code" of the Governance section of this report for further information.

### Performance Assessment

The Board determines the Executive Director's variable remuneration (whereby the Executive Director has not taken part in the discussions and decision-making by the Board) based on an annual performance assessment and professional judgment. Variable remuneration is linked to the individual's performance against a set of financial and non-financial goals that supports and is consistent with the Company's strategy and long-term interests.

These goals include, among other topics, performance, business development, strategy, investor relations, and general management. Risk alignment is considered in target setting to promote sound and effective risk management. Variable remuneration is paid out according to how the Company's business develops, the scope of the Executive Director's achievement, and the realization of the Company's general objectives.

In early 2022, the Board approved a set of company goals for our Executive Director, containing both financial and non-financial KPIs in the following functional areas:

- Clinical & Development
- Operational & Commercial
- People
- Strategic & Financial

| Performance Criteria Functional Area | Criteria Weight | On-target Performance | Actual Performance | Measured Performance |
|---|---|---|---|---|
| Clinical & Development | 40% | 100% | 87% | 35% |
| Operational & Commercial | 20% | 100% | 92% | 18% |
| People | 20% | 100% | 110% | 22% |
| Strategic & Financial | 20% | 100% | 110% | 22% |
| **Total** | | | | **97%** |
| **Corresponding amount** | | | | **398** |

Only the on-target performance and corresponding award was formalized.

After conclusion of the financial year, the Board assesses to what extent the KPIs have been met and determines the measured performance percentage and corresponding amount for the Executive Director. Bonus compensation is at the discretion of the Remuneration Committee and, ultimately, the Board.

On the recommendation of the Remuneration Committee, the Board recognized the outstanding achievements realized and in consideration of performance across the range of KPIs, granted the CEO a 97% bonus payout relating to 2022.

### Non-Executive Director Remuneration

It should be in the Non-Executive Directors' interest to focus on the Company's sustainable and long-term successful development. As such, the Company believes that fixed remuneration for the Non-Executive Directors is effective. Regardless of their remuneration, all Non-Executive Directors are entitled to reimbursement for their travel expenses.

The fees are as follows:

| EUR'000 | Chairman | Member |
|---|---|---|
| Board of Directors | 45 | 45 |
| Audit Committee | 12 | 6 |
| Compensation Committee | 10 | 5 |
| Nomination and Corporate Governance Committee | 8 | 4 |

### Determination of Non-Executive Directors' Remuneration

Non-Executive Director remuneration for 2022 amounted to:

| Name | Board | Audit Committee | Compensation Committee | Nomination & Corporate Governance Committee | Total 2021 Compensation |
|---|---|---|---|---|---|
| **Jan Øhrstrøm** | Chair | | Chair | Chair | 208,134[a] |
| **Gregoire Courtine** | | | | | 300,725[b] |
| **Fred Colen** | | Member | Member | | 59,839[c] |
| **Kristina Dziekan** | | Member | | | 26,538 |
| **Vivian Riefberg[c]** | | | Member | | 25,275[d] |

Non-Executive Director remuneration for 2021 amounted to:

| Name | Board | Audit Committee | Compensation Committee | Nomination & Corporate Governance Committee | Total 2021 Compensation |
|---|---|---|---|---|---|
| **Jan Øhrstrøm** | Chair | | Chair | Chair | 538,197[e] |
| **Gregoire Courtine** | | | | | 980,918[f] |
| **Fred Colen** | | Member | Member | | 96,820[g] |

In 2022, the Company's new Interim Director (Vivian Riefberg) was awarded 16,000 share options as a signing bonus under the existing long-term incentive plan. This deviation was approved by the Board on recommendation of the Compensation Committee.

This grant is considered necessary to serve the Company's long-term interests and sustainability and to ensure its viability; such a grant is instrumental to attracting and retaining a highly qualified non-Executive Director, especially when compared to compensation practices in the U.S. This decision deviates from Best Practice Provision 3.3.2 of the CGC, which recommends not providing equity awards as part of a non-Executive Director's compensation. (See "Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code.")

### Liability Insurance (D&O) & Indemnity

The Company maintains D&O insurance covering the Executive Directors and all Non-Executive Directors.

Pursuant to Article 23 of the Articles of Association, the Directors are indemnified, held harmless, and reimbursed by the Company for all expenses, financial effects of judgments, fines, and amounts paid in settlement actually and reasonably incurred by them in connection with an action, suit, proceeding, or investigation against them in their capacity as Executive or Non-Executive Director.

*a: Compensation includes cost of 2022 vesting of stock options (EUR 94,755) and the reimbursement of travel expenses (EUR 5,379).*
*b: Compensation includes the remuneration paid in relation to his role as CSO (EUR 146,124), as well as the vesting of stock options under the long-term incentive plan (EUR 154,601).*
*c: Compensation includes the reimbursement of travel expenses (EUR 3,839).*
*d: Interim Director (expected to be nominated for appointment as Director at our 2023 Annual General Meeting). Compensation includes cost of vesting of stock options awarded (EUR 6,941) and the reimbursement of travel expenses (EUR 5,291)*
*e: Compensation includes the vesting of the Employee Investment Plan on IPO, the 2021 expense for the one-off option award of 38,000 shares that was approved by the board and the reimbursement of travel expenses.*
*f: Compensation includes the remuneration paid in relation to his role as CSO (EUR 118,522), as well as the vesting of the Employee Investment Plan on IPO (EUR 807,161) and stock options granted in December 2021 under the long-term incentive plan (EUR 7,021).*
*g: Compensation includes the vesting of the Employee Investment Plan on IPO.*

### Historical Development

The table below provides an overview of the annual compensation of the Executive Director and full-time equivalent (FTE) employees for the financial years 2022 and 2021. The amounts mentioned in the table are gross amounts before the impact of social-security or income-tax deductions.

| EUR'000 | 2022 | 2021 | Change % |
|---|---|---|---|
| Net loss of the period | 32,772 | 34,314 | -2% |
| Executive Director | 1,430 | 3,331 | -57%[a] |
| Average FTE employees | 86.6 | 65.85 | 31% |
| Employee costs of FTE employees | 18,282 | 15,519 | 18% |
| Cost per FTE | 212 | 236 | -10% |
| Pay Ratio | 7 | 14 | -52% |
| Non-Executive Directors | 621 | 1,616 | -62% |

### Pay Ratio

Based on Best Practice Provision 3.4.1 of the CGC, the Company shall disclose the pay ratio between the remuneration of the Executive Directors and that of a representative reference group of Company employees and, if applicable, comment on any important variation in pay ratios compared to the previous financial year.

The reference group includes the Company's entire workforce expressed in the form of full-time equivalent employees (FTE). The full-time equivalence of each employee is calculated based on the number of hours an employee works in each period, compared to the maximum number of hours/periods allowed, as per the local law prevalent in the country of operation. As of 31 December 2022, there were 96.1 FTEs (2021: 76.7).

Pay ratios are calculated based on the average remuneration received by employees of the reference group. The remuneration taken into account is that received during the year concerned. If all or part of the remuneration was paid in a foreign currency, the exchange rate used was the average exchange rate of the relevant currency into Euros for the year ending 31 December 2022.

The Company used both fixed and variable remuneration components in determining the pay ratio for a given year. The pay ratio disclosed by the Company reflects the previous financial year. The average Executive Director-to-employee pay ratio stands at 7 in 2022, compared with 14 in 2021. The variance year-on-year is due to the successful IPO in October 2021 that positively impacted the performance-based remuneration and triggered the accelerated vesting of the Employee Investment Plan.

# Financials

# Consolidated Statement of Profit & Loss

| | | For the Year Ended 31 December | |
|---|---|---|---|
| *All amounts in EUR '000* | **Notes** | **2022** | **2021** |
| Grants & Other Income | 2.1 | **2,148** | **1,399** |
| **Total Revenues & Other Income** | | **2,148** | **1,399** |
| Research & Development Expenses | 2.2,2.8 | (13,138) | (10,618) |
| Clinical & Regulatory Expenses | 2.3,2.8 | (5,747) | (4,775) |
| Marketing & Market Access Expenses | 2.4,2.8 | (1,951) | (1,516) |
| Patent fees & Related Expenses | 2.5,2.8 | (1,549) | (1,361) |
| Quality Assurance Expenses | 2.6,2.8 | (1,228) | (993) |
| General & Administrative Expenses | 2.7,2.8 | (10,563) | (10,667) |
| **Total Operating Expenses** | | **(34,176)** | **(29,931)** |
| **Operating Loss for the Period** | | **(32,028)** | **(28,532)** |
| Financial income | 4.5 | 62 | – |
| Financial expense | 4.5 | (1,572) | (5,713) |

| | | | |
|---|---|---|---|
| **Net Finance Expense** | | **(1,510)** | **(5,713)** |
| **Loss for the Period Before Taxes** | | **(33,538)** | **(34,245)** |
| Income Tax expense | 2.10 | 766 | (69) |
| **Net Loss for the Period** | | **(32,772)** | **(34,314)** |
| **Attributable to:** | | | |
| Equity holders of the parent | | **(32,772)** | **(34,314)** |
| Non-controlling interests | | **–** | **–** |
| | | **(32,772)** | **(34,314)** |
| **Earnings Per Share (EUR):** | | | |
| Basic earnings per share: | 4.1 | (1.09) | (3.62) |
| Diluted earnings per share: | 4.1 | (1.09) | (3.62) |

# Consolidated Statement of Comprehensive Income

| *All amounts in EUR '000* | Notes | For the Year Ended 31 December 2022 | 2021 |
|---|---|---|---|
| **Net Loss for the Period** | | **(32,772)** | **(34,314)** |
| Remeasurement of post-employment benefits | 5.0, 2.10 | 427 | (714) |
| **Other comprehensive income that will not be reclassified to profit or loss in subsequent periods (net of tax)** | | **427** | **(714)** |
| Currency translation differences | | 602 | 249 |
| **Other comprehensive income that will be reclassified to profit or loss in subsequent periods (net of tax)** | | **602** | **249** |
| **Total Comprehensive Result for the Year, Net of Tax** | | **(31,743)** | **(34,779)** |
| Attributable to: | | | |
| Equity holders of the parent | | **(31,743)** | **(34,779)** |
| Non-controlling interests | | **–** | **–** |
| | | **(31,743)** | **(34,779)** |

# Consolidated Statement of Financial Position

For the Year Ended 31 December

| *All amounts in EUR '000* | Notes | 2022 | 2021 |
|---|---|---|---|
| **Assets** | | | |
| **Non-Current Assets** | | | |
| Intangible assets | 3.0 | 10,158 | 10,029 |
| Property, plant & equipment | 3.1 | 415 | 190 |
| Right of use assets | 3.2 | 1,681 | 2,190 |
| Deferred tax assets | 2.10 | 163 | – |
| | | 12,417 | 12,409 |
| **Current Assets** | | | |
| Indirect tax receivables | 3.3 | 709 | 339 |
| Receivable from related parties | | 251 | 60 |
| Other current assets | 3.4 | 1,456 | 2,546 |
| Fixed term deposits | 3.5 | 20,000 | – |
| Cash and cash equivalents | 3.5 | 41,760 | 89,443 |
| | | 64,176 | 92,387 |
| | | **76,593** | **104,796** |

| | | | |
|---|---|---|---|
| **Equity & Liabilities** | | | |
| **Equity & Reserves** | | | |
| Issued capital | 4.0 | 3,622 | 3,622 |
| Share premium | 4.0 | 155,249 | 155,249 |
| Other reserves* | 4.0 | 2,079 | (214) |
| Retained earnings | | (108,319) | (75,974) |
| **Total Equity Attributable to Shareholders** | | **52,631** | **82,683** |
| **Non-Current Liabilities** | | | |
| Interest-bearing loans | 4.2 | 12,656 | 11,451 |
| Deferred tax liability | 2.10 | 670 | 1,991 |
| Lease liability | 3.2 | 1,294 | 1,741 |
| Post-employment benefits | 5.0 | 1,121 | 1,388 |
| | | **15,741** | **16,571** |
| **Current Liabilities** | | | |
| Income tax liabilities | | 219 | 83 |
| Lease liability | 3.2 | 427 | 473 |
| Trade payables | 3.6 | 1,909 | 952 |
| Other payables | 3.7 | 5,666 | 4,034 |
| | | **8,221** | **5,542** |
| | | **76,593** | **104,796** |

** Other reserves include the foreign currency translation reserve that qualifies as a legal reserve under Dutch Law.*

# Consolidated Statement of Changes in Equity

| *All amounts in EUR '000* | Notes | Issued Capital | Share Premium | Other Reserves* | Retained Earnings | Total Equity |
|---|---|---|---|---|---|---|
| **As at 1 January 2021** | | – | **3,083** | **17,933** | **(53,111)** | **(32,095)** |
| Loss for the year 2021 | | – | – | – | (34,314) | (34,314) |
| Other comprehensive income | | – | – | 249 | (714) | (465) |
| *Total comprehensive result* | | **–** | **–** | **249** | **(35,028)** | **(34,779)** |
| Conversion of preference A-shares | **4.0,4.1** | **–** | **49,467** | **(14,794)** | **–** | **34,673** |
| Reversed stock-split | **4.0** | **2,445** | **(2,445)** | **–** | **–** | **–** |
| Share based payments: EIP | **2.9** | **–** | **–** | **8,494** | **–** | **8,494** |
| Share based payments: EIP accelerated vesting | **2.9** | **–** | **–** | **(12,165)** | **12,165** | **–** |
| Conversion of CLA | **4.0,4.1** | **391** | **30,731** | **–** | **–** | **31,122** |
| Issue of share capital: EPFL option | **4.0** | **32** | **–** | **–** | **–** | **32** |
| Issue of share capital: IPO | **4.0** | **708** | **74,517** | **–** | **–** | **75,225** |
| Issue of share capital: Over-allotment | **4.0** | **46** | **4,835** | **–** | **–** | **4,881** |
| Capitalization of costs related to IPO and issue of new shares | **4.0** | **–** | **(4,939)** | **–** | **–** | **(4,939)** |
| Share based payments: LTIP | **2.9** | **–** | **–** | **69** | **–** | **69** |
| **As at 31 December 2021** | **4.0** | **3,622** | **155,249** | **(214)** | **(75,974)** | **82,683** |
| **As at 1 January 2022** | | **3,622** | **155,249** | **(214)** | **(75,974)** | **82,683** |
| Loss for the year 2022 | | – | – | – | (32,772) | (32,772) |
| Other comprehensive income | | – | – | 602 | 427 | 1,029 |
| *Total comprehensive result* | | – | – | 602 | (32,345) | (31,743) |
| Share based payments: LTIP | **2.9** | – | – | 1,691 | – | 1,691 |
| **As at 31 December 2022** | **4.0** | **3,622** | **155,249** | **2,079** | **(108,319)** | **52,631** |

** Other reserves include the foreign currency translation reserve that qualifies as a legal reserve under Dutch Law.*

# Consolidated Statement of Cash Flows

| | | For the Year Ended 31 December | |
|---|---|---|---|
| *All amounts in EUR '000* | **Notes** | **2022** | **2021** |
| **Cash Flows from Operating Activities** | | | |
| **Loss for the Period Before Taxes** | | **(33,538)** | **(34,245)** |
| Adjusted for: | | | |
| ◦ Depreciation and impairment of property, plant and equipment and right-of-use assets | 3.1, 3.2 | 735 | 329 |
| ◦ Share based payment transaction expense | 2.9 | 1,691 | 8,564 |
| ◦ Post-employment benefits | | 154 | 246 |
| ◦ Net finance costs | | 1,510 | 5,713 |
| ◦ Net foreign exchange differences | | – | (43) |
| ◦ Other non-cash items | | 106 | (2) |
| Changes in working capital:<br>Increase (-) Decrease (+) in Trade and other receivables | | 140 | (2,358) |
| Increase (+) Decrease (-) in Trade and other payables | | 2,813 | 2,097 |

| | | | |
|---|---|---|---|
| Interests received | | 15 | – |
| Interests paid | | (229) | (146) |
| Income tax paid | | (49) | (14) |
| Bank Charges paid | 4.5 | (33) | (17) |
| **Net cash generated /(used) from operating activities** | | **(26,685)** | **(19,874)** |
| **Cash flows from investing activities** | | | |
| Investments in fixed assets | 3.1 | (386) | (91) |
| Investments in intangible fixed assets | 3.0 | (31) | (2,233) |
| Investment in fixed term deposits | 3.5 | (20,000) | – |
| **Net cash generated/(used) from investing activities** | | **(20,417)** | **(2,324)** |
| **Cash flows from financing activities** | | | |
| Proceeds from interest-bearing loans | 4.2 | – | 30,000 |
| Payment of principal portion of lease liabilities | 3.2 | (557) | (144) |
| Proceeds from issuance of shares | | – | 80,106 |
| Transaction costs on issuance of shares | 4.0 | – | (4,601) |
| **Net cash generated/(used) from financing activities** | | **(557)** | **105,361** |
| **Movement in cash and cash equivalents** | | | |
| | | **89,443** | **6,382** |
| Cash and cash equivalents at 1 January | | (24) | (100) |
| Effect of exchange rates on cash and cash equivalents | | **(47,659)** | **83,162** |
| Changes in cash and cash equivalents during the period | | | |
| **Cash and cash equivalents at 31 December** | 3.5 | **41,760** | **89,443** |

# Notes to the Consolidated Financial Statements

## 1. General Information & Basis of Preparation

### 1.0 Corporate Information

**General**

ONWARD Medical B.V. was a Dutch private company with limited liability (besloten vennootschap met beperkte aansprakelijkheid), incorporated on 20 November 2015. On 21 October 2021 (the First Trading Date) the Company completed a corporate conversion, converting into a public limited company under Dutch law (naamloze vennootschap). The legal name changed to Onward Medical N.V. ("ONWARD"). The registered office is located at Schimmelt 2, Eindhoven, the Netherlands. ONWARD Medical N.V. is registered in the Commercial Register of the Chamber of Commerce under number 64598748.

ONWARD and its subsidiaries (the "Group") are developing both an Implantable Neuro-stimulation System (INS) and a non-invasive system for electrical stimulation of specific areas of the spinal cord.

The financial statements for the year ended 31 December 2022 have been prepared by the board of directors and were authorized for issue on 27 March 2023. The financial statements will be submitted for adoption to the General Meeting on 8 May 2023.

## 1.1 Group Information

**Information about subsidiaries**

The consolidated financial statements of the Group include:

- ONWARD Medical SA, Switzerland (holding 100%)
- ONWARD Medical Inc, United States of America (holding 100%)

## 1.2 Basis of Preparation

The Consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards (IFRS) and IFRIC interpretations as adopted by the European Union and with Part 9 of Book 2 of the Dutch Civil Code.

The Consolidated financial statements have been prepared on a historical cost basis. Income and expenses are accounted for on an accrual basis. The Consolidated financial statements provide comparative information in respect of the previous period. Certain prior year amounts have been reclassified for consistency with the current year presentation. Refer to section 1.8 below.

The Consolidated financial statements are presented in euros and all values are rounded to the nearest thousand (EUR 000), except when otherwise indicated, and for the number of shares and the per share amount. Due to rounding, amounts may not add up to totals provided.

## 1.3 Basis of Consolidation

The Consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 31 December 2022. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. Specifically, the Group controls an investee if and only if the Group has:

- Power over the investee (i.e. existing rights that give it the current ability to direct the relevant activities of the investee)
- Exposure, or rights, to variable returns from its involvement with the investee, and
- The ability to use its power over the investee to affect its returns

The Group re-assesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the statement of comprehensive income from the date the Group gains control until the date the Group ceases to control the subsidiary.

Profit or loss and each component of other comprehensive income (OCI) are attributed to the equity holders of the parent of the Group. When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with the Group's accounting policies. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

## 1.4 Going Concern

In determining the appropriate basis for preparing the financial statements for the year ended 31 December 2022, Management considered the cash flow forecasts over a time horizon of one year after the date of these financial statements. The 2023 cash flow forecasts, include significant expenses and cash outflows in relation to -among others- the ongoing clinical trials, the continuation of research and development projects and FDA submission and approval for the ARC$^{EX}$ indication. As at 31 December 2022 the Company had cash and cash equivalents of EUR 42M and fixed term deposits with a maturity of less than 12 months of EUR 20M. The Company believes that this cash position will be sufficient to meet the Company's capital requirements and fund its operations for at least 12 months as from the date of this Annual Report.

Inherent uncertainties in these forecasts may have an impact on the Company's cash position. To continue development and reach commercialization as planned, the Company will need to attract additional funding in future. The Company's long-term success and existence is contingent on achieving FDA approval and CE mark of its products.

In view of the above, and notwithstanding a loss brought forward of EUR 108M as of 31 December 2022 the application of the valuation rules in the assumption of a "going concern" is justified. As a result, the consolidated financial statements have been prepared on a going concern basis.

## 1.5 Summary of Other Significant Accounting Policies

### a) Business Combinations

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, measured at acquisition date fair value and the amount of any non-controlling interest in the acquiree. For each business combination, the Group elects whether to measure the non-controlling interest in the acquiree at fair value or at the proportionate share of the acquirer's identifiable net assets. Acquisition-related costs are expensed as incurred and included in administrative expenses.

When the Group acquires a business, it assesses the financial assets and liabilities assumed for appropriate classification and designation in accordance with the contractual terms, economic circumstances and pertinent conditions as at the acquisition date. This includes the separation of embedded derivatives in host contracts by the acquiree.

If the business combination is achieved in stages, any previously held equity interest is re-measured at its acquisition date fair value and any resulting gain or loss is recognized in profit or loss. It is then considered in the determination of goodwill.

Any contingent consideration to be transferred by the acquirer will be recognized at fair value at the acquisition date. Contingent consideration classified as an asset or liability that is a financial instrument and within the scope of IFRS 9 Financial Instruments, is measured at fair value with changes in fair value recognized in the statement of profit or loss in accordance with IFRS 9. Other contingent consideration that is not within the scope of IFRS 9 is measured at fair value at each reporting date with changes in fair value recognized in profit and loss.

### b) Current Versus Non-Current Classification

The Group presents assets and liabilities in the statement of financial position based on current/non-current classification. An asset is current when it is:

- Expected to be realized or intended to be sold or consumed in normal operating cycle
- Held primarily for the purpose of trading
- Expected to be realized within twelve months after the reporting period, or
- Cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period

All other assets are classified as non-current.

A liability is current when:

- It is expected to be settled in normal operating cycle
- It is held primarily for the purpose of trading
- It is due to be settled within twelve months after the reporting period, or
- There is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period

The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified as non-current assets and liabilities.

**c) Foreign Currencies**

The Group's consolidated financial statements are presented in euros, which is also the parent company's functional currency. For each entity, the Group determines the functional currency and items included in the financial statements of each entity are measured using that functional currency.

**Transactions & Balances**

Transactions in foreign currencies are initially recorded by the Group entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are retranslated at the functional currency spot rate of exchange at the reporting date.

Differences arising on settlement or translation of monetary items are recognized in profit or loss with the exception of monetary items that are designated as part of the hedge of the Group's net investment of a foreign operation. These are recognized in other comprehensive income until the net investment is disposed of, at which time, the cumulative amount is reclassified to profit or loss. Tax charges and credits attributable to exchange differences on those monetary items are also recorded in other comprehensive income.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates as at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value is determined. The gain or loss arising on translation of non-monetary items measured at fair value is treated in line with the recognition of gain or loss on change in fair value of the item (i.e., translation differences on items whose fair value gain or loss is recognized in other comprehensive income or profit or loss are also recognized in other comprehensive income or profit or loss, respectively).

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising on the acquisition are treated as assets and liabilities of the foreign operation and translated at the spot rate of exchange at the reporting date.

**Group Companies**

On consolidation, the assets and liabilities of foreign operations are translated into euros at the rate of exchange prevailing at the reporting date and their income statements are translated at the monthly average exchange rates.

The exchange differences arising on translation for consolidation are recognized in other comprehensive income. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognized in profit or loss.

### 1.6 Significant Accounting Judgments, Estimates & Assumptions

The preparation of the Group's consolidated financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and the disclosure of contingent liabilities, at the end of the reporting period. However, uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of the asset or liability affected in future periods.

The Group based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of revision and the future periods if the revision affects both current and future periods.

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, that are most relevant to the carrying amounts of assets and liabilities within the next financial year, are included in each of the respective notes as referenced below:

| | |
|---|---|
| Research & Development | **(Note 2.2)** |
| Share-Based Payments | **(Note 2.9)** |
| Impairment of Intangible Assets | **(Note 3.0)** |
| Post-Employment Benefits | **(Note 5.0)** |
| Taxes | **(Note 2.10)** |

### 1.7 New Accounting Standards & Developments

#### 1.7.1 New and Amended Standards and Interpretations

Several amendments applied for the first time in 2022:

- Amendments to IFRS 3: Reference to the Conceptual Framework, effective 1 January 2022
- Amendments to IAS 16: Property, Plant and Equipment Proceeds before intended use, effective 1 January 2022
- Amendments to IAS 37: Onerous Contracts – Costs of Fulfilling a Contract, effective 1 January 2022
- Annual Improvement Project IFRS 1 First-time Adoption of International Financial Reporting Standards – Subsidiary as a first-time adopter, effective 1 January 2022
- Annual Improvement Project IFRS 9 Financial Instruments – Fees in the '10 per cent' test for derecognition of financial liabilities, effective 1 January 2022
- Annual Improvement Project IAS 41 Agriculture – Taxation in fair value measurements, effective 1 January 2022

None of these had a material impact on the consolidated financial statements of the Group in 2022.

#### 1.7.2 Standards Issued But Not Yet Effective

The new and amended standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Group's financial statements are listed below. The Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective. The Group intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

- Classification of Liabilities as Current or Non-current - Amendments to IAS 1, effective 1 January 2024
- Disclosure of Accounting Policies - Amendments to IAS 1 and IFRS Practice Statement 2, effective 1 January 2023
- Definition of Accounting Estimates - Amendments to IAS 8, effective 1 January 2023
- Deferred Tax related to Assets and Liabilities arising from a Single Transaction – Amendments to IAS 12, effective 1 January 2023

The nature and impact of each of the new standards, amendments and/or interpretations expected to apply to the Group are described below:

**Amendments to IAS 1: Classification of Liabilities as Current or Non-current**

In January 2020 and October 2022, the Board issued amendments to IAS 1 Presentation of Financial Statements to specify the requirements for classifying liabilities as current or non-current. The amendments clarify:

- What is meant by a right to defer settlement
- That a right to defer must exist at the end of the reporting period
- That classification is unaffected by the likelihood that an entity will exercise its deferral right
- That only if an embedded derivative in a convertible liability is itself an equity instrument would the terms of a liability not impact its classification.
- That disclosure should be provided when a liability arising from a loan agreement is classified as non-current and the entity's right to defer settlement is contingent on compliance with future covenants within twelve months. This disclosure must include information about the covenants and the related liabilities.

The amendments are effective for annual reporting periods beginning on or after 1 January 2024 and must be applied prospectively. The Group is currently assessing the impact the amendments will have on current practice and whether the existing loan agreement may require renegotiation.

**Disclosure of Accounting Policies - Amendments to IAS 1 and IFRS Practice Statement 2**

In February 2021, the IASB issued amendments to IAS 1 and IFRS Practice Statement 2 Making Materiality Judgments, in which it provides guidance and examples to help entities apply materiality Judgments to accounting policy disclosures. The amendments aim to help entities provide accounting policy disclosures that are more useful by replacing the requirement for entities to disclose their 'significant' accounting policies with a requirement to disclose their 'material' accounting policies and adding guidance on how entities apply the concept of materiality in making decisions about accounting policy disclosures.

The amendments to IAS 1 are applicable for annual periods beginning on or after 1 January 2023 with earlier application permitted. Since the amendments to the Practice Statement 2 provide non-mandatory guidance on the application of the definition of material to accounting policy information, an effective date for these amendments is not necessary.

The Group is currently assessing the impact of the amendments to determine the impact they will have on the Group's accounting policy disclosures.

**Definition of Accounting Estimates - Amendments to IAS 8**

In February 2021, the IASB issued amendments to IAS 8, in which it introduces a definition of 'accounting estimates'. The amendments clarify the distinction between changes in accounting estimates and changes in accounting policies and the correction of errors. Also, they clarify how entities use measurement techniques and inputs to develop accounting estimates.

The amendments are effective for annual reporting periods beginning on or after 1 January 2023 and apply to changes in accounting policies and changes in accounting estimates that occur on or after the start of the effective period. Earlier application is permitted as long as this fact is disclosed.

The Group is currently assessing the amendments to determine the impact it will have.

### Amendments to IAS 12 - Deferred Tax related to Assets and Liabilities arising from a Single Transaction

In May 2021, the Board issued amendments to IAS 12, which narrow the scope of the initial recognition exception under IAS 12, so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences. The amendments clarify that where payments that settle a liability are deductible for tax purposes, it is a matter of judgment (having considered the applicable tax law) whether such deductions are attributable for tax purposes to the liability recognized in the financial statements (and interest expense) or to the related asset component (and interest expense). This judgment is important in determining whether any temporary differences exist on initial recognition of the asset and liability. Under the amendments, the initial recognition exception does not apply to transactions that, on initial recognition, give rise to equal taxable and deductible temporary differences. It only applies if the recognition of a lease asset and lease liability (or decommissioning liability and decommissioning asset component) give rise to taxable and deductible temporary differences that are not equal. An entity should apply the amendments to transactions that occur on or after the beginning of the earliest comparative period presented. Effective for annual periods beginning on or after 1 January 2023.

The Group is currently assessing the amendments to determine the impact it will have.

## 1.8 Changes in Accounting Policies & Disclosures

### 1.8.1 Change in Disclosure in the Consolidated Statement of Profit & Loss 2021

The Group has reassessed the presentation of line items in the consolidated statement of profit and loss and decided to present the Science expenses as a component of Research & Development expenses as opposed to a separate cost category on the face of the Statement of Profit and Loss. Science expenses consist primarily of the costs of sponsored research activities that are undertaken by universities with which ONWARD collaborates. Since its inception, ONWARD has had a close working relationship with two of the founders, Grégoire Courtine, Professor at EPFL and Jocelyne Bloch, Neurosurgeon at CHUV, Professor at Université de Lausanne. The activities between the Company and EPFL are formalized in research agreements which govern the activities sponsored by the Company. In addition to these scientific research expenses also the consultancy expenses and related shared-based payment expenses for Grégoire Courtine and Jocelyne Bloch are included. Science expenses therefore directly relate to and support our ongoing Research & Development efforts. This presentation is also in line with companies within the industry and will therefore enhance comparability.

| | Reported: 2021 | Restated: 2021 | Change |
|---|---|---|---|
| Science expenses | 2,686 | – | (2,686) |
| Research & Development expenses | 7,932 | 10,618 | 2,686 |

The following note was restated:

| | Reported: 2021 | Restated: 2021 | Change |
|---|---|---|---|
| *2.3 Research & Development expenses** | | | |
| Staff costs | 5,218 | 7,773 | 2,555 |
| Outsourced cost | 2,715 | 2,846 | 131 |
| | **7,932** | **10,618** | **2,686** |

And the following note has been removed:

| | Reported: 2021 | Restated: 2021 | Change |
|---|---|---|---|
| *2.2 Science expenses* | | | |
| Staff costs | 2,555 | – | (2,555) |
| Outsourced cost | 131 | – | (131) |
| | **2,686** | **–** | **(2,686)** |

** Note 2.2 in 2022*

## 2.Results of the Year

### 2.0 Segment Reporting

Based on the organizational structure, as well as the nature of financial information available and reviewed by the Company's chief operating decision makers to assess performance and make decisions about resource allocations, the Company has concluded that its total operations represent one reportable segment and that the consolidated disclosures address the requirements.

| | 2022 | 2021 |
|---|---|---|
| Non-current assets | | |
| Netherlands | 61 | 197 |
| Switzerland | 2,194 | 2,177 |
| United States of America | 10,162 | 10,035 |
| **Non-current assets** | **12,417** | **12,409** |

### 2.1 Revenues & Other Income

**Accounting Policy:** Government subsidies are recognized where there is reasonable assurance that the subsidy will be received, and all attached conditions will be complied with. When the subsidy relates to an expense item, it is recognized as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed. Any outstanding receivables related to these subsidies are recorded as grants receivable. The government subsidies are presented on a gross basis except for the WBSO ("Wet Bevordering Speur & Ontwikkeling") that is presented on a net basis with the expensed amount for personnel expenses.

| | 2022 | 2021 |
|---|---|---|
| Government subsidies (EU) | 2,044 | 1,399 |
| Other income | 104 | – |
| **Total revenues and other income** | **2,148** | **1,399** |

Government subsidies have been received for the research and development of several development projects. There are no unfulfilled conditions or contingencies attached to these subsidies.

| | | Recognized | |
|---|---|---|---|
| **Grants** | **Total Grant*** | **2022** | **2021** |
| CONFIRM | **416** | **(12)** | **139** |
| BESTABLE | **100** | **–** | **16** |
| SWISS LOCAL (one -offs) | **–** | **85** | **41** |
| PREP2GO | **348** | **104** | **139** |
| DARPA | **3,172** | **1,412** | **981** |
| ZonMW | **250** | **83** | **83** |
| EISMEA – Reverse Paralysis | **1,228** | **273** | **–** |
| EISMEA - NEMO BMI | **1,020** | **85** | **–** |
| Eurostars Impulse | **500** | **14** | **–** |
| **Total**** | | **2,044** | **1,399** |

** Please refer to the terms and conditions of the subsidies included below.*
*** Except for the Swiss local grant received by ONWARD Medical SA (In Switzerland), all other grants were received by ONWARD Medical N.V. (In the Netherlands).*

## Terms & Conditions

### CONFIRM

This Eurostars funding agreement with the Swiss Innovation Agency Innosuisse for a total amount of EUR 416k started in May 2019 and ended in October 2021, with follow up reporting resulting in the additional 25.75% granting of the allocated amount. The remainder of the grant was receivable in 2022 after submission of the final report. Due to lesser expenses declared, the final amount was decreased. In this project, ONWARD collaborated with Inomed A.G., Universitätsklinikum Heidelberg and EPFL to develop an intra-operative neuromonitoring system and algorithms facilitating the surgical implantation of ARC$^{IM}$.

### BESTABLE

This Eurobench funding agreement with PKF ATTEST INNCOME S.L. and the Spanish National Research Council CSIC for a total amount of EUR 100k started in September 2019 and ended in December 2021. An amount equal to 85% of the grant is paid during the grant period in tranches in 2019, 2020 and 2021. The remaining 15% of the total grant amount is payable after evaluation of the final report. In this project, ONWARD is collaborating with the Technical University of Delft and the University Rehabilitation Institute to develop a benchmarking system for assessment of balance performance.

### PREP2GO

This Eurostars funding agreement with the Netherlands enterprise agency RVO for a total amount of EUR 348k started in April 2020 and ends in September 2022. An amount equal to 90% of the grant is paid during the grant period in tranches in 2020, 2021 and 2022. The remaining 10% of the grant is payable after evaluation of the final report. In this project, ONWARD is collaborating with Zurich Medtech A.G., IT'IS Foundation, Universitair Medisch Centrum Utrecht and EPFL to automatize the simulation framework that was developed in the RESTORE project, to facilitate the pre-operative planning for ARC Therapy for clinicians.

### DARPA

The DARPA grant is a five-year project that started in October 2020. The award has been divided into 3 phases. The funding agreement for phase 1 and phase 2 was approved for a total amount of EUR 3.172M (or USD 3.402M). The grant amounts are being charged on a monthly basis over the period based on actual costs incurred. In this project, ONWARD is collaborating with a large consortium of academic partners, companies, and consultants to develop a new clinical intervention to modulate blood pressure and spinal cord perfusion and oxygenation in the hours following SCI. This correspond to a roadmap development of ARC$^{IM}$ to be used in the hours following SCI.

### ZonMW

This Dutch funding agreement is with the Netherlands Organisation for Health Research and development for a total amount of EUR 250k that started in January 2021 and ends in January 2024. An amount equal to 80% of the grant is being paid during the grant period in three equal tranches in 2021, 2022 and 2023. The remaining 20% of the grant will be paid after submission of the final report. In this project, ONWARD is collaborating with the University of Bordeaux, CHUV and EPFL to develop a research interface for ARC$^{IM}$ and evaluating its use to alleviate locomotor deficits in Parkinson disease.

### EISMEA – Reverse Upper- & Lower-Limb Paralysis

The European Innovation Council and SMEs Executive Agency (EISMEA) awarded a grant to support the development of an innovative Brain-Spine Interface technology for restoring mobility and upper limb function. The EUR 3.6M grant was awarded to ONWARD and its research partners EPFL; CEA-Clinatec and Sint Maartenskliniek. Under the terms of the award, ONWARD receives EUR 1.2M. The project started 1 May 2022 and has an end date of 30 April 2025, a duration of 36 months. ONWARD has received 75% as prefinancing, an additional 15% is receivable 90 days after the first periodic reporting and the final payment 90 days after receiving the second periodic reporting.

### EISMEA – NEMO BMI

The European Innovation Council and SMEs Executive Agency (EISMEA) awarded a grant to support the development of Motor Brain-Machine Interfaces (BMIs). BMIs translate brain neural signals into commands to external effectors. The NEMO BMI project will conduct the exploration of assistance-free and easy to use portable neuroprosthetics including wireless neuronal activity recorder, a real-time neuronal activity decoder based on integrated technologies, and a spinal cord stimulator. The EUR 3.8M grant was awarded to ONWARD and its research partners Ecole Polytechnique Federale de Lausanne (EPFL), Commissariat a l Energie Atomique et aux energies alternatives (CEA) and Institute of Information and Communication Technologies (IICT). Under the terms of the award, ONWARD receives EUR 1M. The project started 1 October 2022 and has an end date of 30 September 2025, a duration of 36 months. ONWARD has received 75% as prefinancing, an additional 15% (up to 90% of the total grant) is receivable 90 days after the first periodic reporting and the final payment is receivable 90 days after receiving the second periodic reporting.

### Eurostars – Impulse

The Eurostars Independent Evaluation Panel has provided a subsidy for a total amount of EUR 500k that started 1 December 2022 and ends 30 November 2025, a duration of 36 months. The Impulse project focuses on closed-loop control of blood pressure for people with spinal cord injury.

## 2.2 Research & Development Expenses

**Accounting Policy:** Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset when the Group can demonstrate:

- The technical feasibility of completing the intangible asset so that it will be available for use or sale
- Its intention to complete and its ability to use or sell the asset
- How the asset will generate future economic benefits
- The availability of resources to complete the asset
- The ability to measure reliably the expenditure during development
- The ability to use the intangible asset generated

**Significant Estimate:** The Group has evaluated the nature of the project research and development costs and concluded that all expenses incurred were related to research and pre-development of future products. Therefore, all costs have been expensed and are recognized in the statement of profit and loss.

| | 2022 | 2021 |
|---|---|---|
| Staff costs | 8,385 | 7,773 |
| Outsourced cost | 4,753 | 2,846 |
| | **13,138** | **10,618** |

The Company's research and development expenses consist primarily of the cost of external suppliers and third-party contractors involved in the design and development of the ARC$^{EX}$ and ARC$^{IM}$ systems as well as the employee related expenses for research and development, including salaries and benefits. The increase in 2022 is driven by advancements made on our ARC$^{EX}$ and ARC$^{IM}$ platforms.

## 2.3 Clinical & Regulatory Expenses

| | 2022 | 2021 |
|---|---|---|
| Staff costs | 3,204 | 2,905 |
| Outsourced cost | 2,543 | 1,871 |
| | **5,747** | **4,775** |

The Company's clinical and regulatory expenses consist of the employee related expenses including salaries and benefits for employees working on clinical trials. Clinical expenses in 2022 primarily relate to the completion of the Up-LIFT pivotal and LIFT Home clinical trials.

## 2.4 Marketing & Market Access Expenses

| | 2022 | 2021 |
|---|---|---|
| Staff costs | 949 | 916 |
| Outsourced cost | 1,002 | 600 |
| | **1,951** | **1,516** |

The Company's marketing and market access expenses include the investigating activities on the future therapy reimbursement performed by third party consultants and attendance of key events to create awareness within the SCI community of our ARC therapies and technology.

## 2.5 Patent fees & Related Expenses

| | 2022 | 2021 |
|---|---|---|
| Staff costs | 400 | 329 |
| Outsourced cost | 1,149 | 1,032 |
| | **1,549** | **1,361** |

The Company's patents fees and related expenses include the cost for patent prosecution applications, consulting fees for new innovative ideas as well as annuity maintenance fees and license fees for existing ideas as well as related employee expenses, including salary and benefits in the area of business development.

## 2.6 Quality Assurance Expenses

| | 2022 | 2021 |
|---|---|---|
| Staff costs | 1,045 | 960 |
| Outsourced cost | 183 | 33 |
| | **1,228** | **993** |

Quality assurance expenses consist primarily of quality control, quality assurance and regulatory expenses. These expenses include employee expenses, including salary benefits for personnel, consulting, testing and travel expenses.

## 2.7 General & Administrative Expenses

| | 2022 | 2021 |
|---|---|---|
| Staff costs | 4,299 | 5,968 |
| Other operating expenses | 5,529 | 4,370 |
| Depreciation and amortization expense | 735 | 329 |
| | **10,563** | **10,667** |

The Company's general and administrative expenses consist of employee expenses, including salary and benefits for personnel and contractors in executive, finance, accounting, tax, and human resources, as well as operating expenses relating to audit, legal and supply chain.

## 2.8 Employee Benefit Expenses

**Accounting Policy:**

**Short-Term Employee Benefits**

Short-term employee benefits include salaries and social security contributions, social taxes, paid vacation and bonuses. They are recognized as expenses for the period in which employees perform the corresponding services. Outstanding payments at the end of the period are shown as other current liabilities.

**Post-Employment Benefits**

Group companies operate various pension schemes. The schemes are funded through payments to insurance companies or trustee-administered funds, determined by periodic actuarial calculations. The Group has both defined benefit and defined contribution plans.

**Defined Contribution Plan**

A defined contribution plan is a pension plan under which the Group pays fixed contributions into a separate entity. The Group has no legal or constructive obligations to pay further contributions if the fund does not hold sufficient assets to pay all benefits to employees relating to employee services in the current and prior periods. For defined contribution plans, the Group pays contributions to publicly or privately administered pension insurance plans on a mandatory, contractual or voluntary basis. The Group has no further payment obligations once the contributions have been paid. The contributions are recognized as personnel expenses in the consolidated income statement when due.

All related expenses are recognized in the consolidated statement of profit and loss. Contributions payable or prepaid contributions as at year-end are recognized under accruals and deferred income, and prepayments and accrued income, respectively.

**Defined Benefit Plan**

The Group operates a defined benefit pension plan in Switzerland, which requires contributions to be made to a separately administered fund. The cost of providing benefits under the defined benefit plan is determined using the projected unit credit method.

Remeasurements, comprising of actuarial gains and losses are recognised in the statement of financial position with a corresponding debit or credit to retained earnings through OCI in the period in which they occur. Remeasurements are not reclassified to profit or loss in subsequent periods.

Past service costs are recognised in profit or loss on the earlier of:

- The date of the plan amendment or curtailment, and
- The date that the Group recognises related restructuring costs

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset. The Group recognises the changes in the net defined benefit obligation due to service costs comprising current service costs, past-service costs, gains and losses on curtailments and non-routine settlements as part of operating expenses and the net interest expense or income as part of net finance costs in the consolidated statement of profit and loss.

**Significant Estimate:** The cost of the defined benefit pension plan and the present value of the pension obligation are determined using actuarial valuations. An actuarial valuation involves making various assumptions that may differ from actual developments in the future. These include the determination of the discount rate, future salary increases, mortality rates and future pension increases. Due to the complexities involved in the valuation and its long-term nature, a defined benefit obligation is sensitive to changes in these assumptions. All assumptions are reviewed at each reporting date.

| | 2022 | 2021 |
|---|---|---|
| Wages and salaries | 11,653 | 7,203 |
| Social security costs | 1,275 | 908 |
| Pension costs – defined benefit plan | 604 | 445 |
| Pension costs – other | 82 | 101 |
| Share based benefit expenses | 1,691 | 8,564 |
| Other labour costs | 2,977 | 1,629 |
| | **18,282** | **18,850** |

As at 31 December 2022, the ONWARD Group employed 96.1 full-time equivalents, including white-collar employees and contractors. The following table presents a breakdown of the Company's full-time equivalents as at 31 December 2022 and 2021:

| | 2022 | 2021 |
|---|---|---|
| Research & Development | 48.8 | 41.8 |
| Clinical & Regulatory | 18.9 | 15.7 |
| Marketing & Market Access | 3.8 | 2.0 |
| Patent fees & Related | 1.0 | 1.0 |
| Quality Assurance | 7.8 | 4.8 |
| General & Administrative | 15.8 | 11.6 |
| | **96.1** | **76.9** |

As of 31 December 2022, the Company had 16.3 full-time equivalents located in the Netherlands (2021: 35.5), 68.3 full-time equivalents located in Switzerland (2021: 32.9) and 11.5 (2021: 8.5) full-time equivalents located in the United States.

## 2.9 Share-Based Payments

**Accounting Policy:** Employees (including senior executives) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (equity-settled transactions).

**Equity-Settled Transactions**

The cost of equity-settled transactions is determined by the fair value at the date when the grant is made using an appropriate valuation model.

That cost is recognized, together with a corresponding increase in other reserves in equity, over the period in which the performance and/or service conditions are fulfilled in employee benefits expense. The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The statement of profit or loss expense or credit for a period represents the movement in cumulative expense recognized as at the beginning and end of that period and is recognized in operating expenses.

No expense is recognized for awards that do not ultimately vest, except for equity-settled transactions for which vesting is conditional upon a market or non-vesting condition. These are treated as vesting irrespective of whether or not the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

When the terms of an equity-settled award are modified, the minimum expense recognized is the expense had the terms not been modified, if the original terms of the award are met. An additional expense is recognized for any modification that increases the total fair value of the share-based payment transaction or is otherwise beneficial to the employee as measured at the date of modification.

**Significant Estimate:** The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Estimating fair value for share-based payment transactions requires determination of the most appropriate valuation model, which is dependent on the terms and conditions of the grant.

### Employee Investment Plan (EIP)

Under the Employee Investment Plan, eligible employees had the opportunity to subscribe for, indirectly via Stichting G-Therapeutics Participaties ("STAK"), an equity stake in ONWARD Medical N.V..Eligible employees were granted depository receipts (DR) via the STAK by means of a deed of issuance. In article 3.2. of the Deed of issuance of the DRs it was determined that a trade sale of the Company or an IPO, of not less than EUR 50M at a price per share to the public not less than EUR 5,- per share, would trigger accelerated vesting of the DR's. The IPO on 21 October 2021 raised EUR 80M at a share price of EUR 12.75. Taking into account the reversed stock split that was contemplated just prior to the IPO the share price would have been EUR 5.10 per share on the outstanding shares prior to the reversed stock split. As both conditions of the IPO event were met, all DR's were deemed fully vested at 21 October 2021. The vesting resulted in a share-based payment expense of EUR 8.5M and a corresponding increase in equity.

### Long-Term Incentive Plan (LTIP)

Following the IPO, and the vesting of the EIP, the Board has agreed upon a new LTIP plan to align the Employee's interest with the interests of the Shareholders and to allow the employee to participate in the long-term growth of the Company. The LTIP is an omnibus plan with the flexibility to issue different type of equity incentives.

ONWARD awarded options over its ordinary shares to participants (referred to as the "Award" or "Grant') on the Grant Dates as specified in the table below. Each option represents the right to receive one ordinary share of ONWARD against payment of the exercise price. The options expire 10 years after the Grant Date and become exercisable on vesting. The Grant is subject to continued provision of services to the Company under a graded vesting schedule, with 25% of the Grant vesting on the first anniversary of the Grant Date, and the remaining 75% of the Grant vesting in equal, monthly tranches over the 3 years following the first anniversary of the Grant Date (i.e.2.083% per month). The number of Options that will vest and become unconditional is only subject to a continued service condition. All options granted have the same conditions. Options do not settle automatically and are exercised at the option of the participant.

| Financial Year | Grant Date | Type of Security | Number of Options Granted | Exercise Price | Expiration Date | Fair Value |
|---|---|---|---|---|---|---|
| **2021** | 15/12/2021 | Stock Options | 612,000 | EUR 9.70 | 15/12/2031 | EUR 4.89 |
| **2022** | 1/4/2022 | Stock Options | 169,800 | EUR 7.64 | 1/4/2032 | EUR4.18 |
| **2022** | 26/9/2022 | Stock Options | 166,350 | EUR 5.70 | 26/9/2032 | EUR 3.19 |

This fair value per option has been applied to the granted awarded for the recognition of the share-based payment expense recognized:

| | 2022 | 2021 |
|---|---|---|
| Share-based payment expense | 1,691 | 69 |
| | **1,691** | **69** |

The table below summarizes the number and weighted average exercise prices (WAEP) of, and movements in, share options during the year:

| | 2022 Number | 2022 WAEP | 2021 Number | 2021 WAEP |
|---|---|---|---|---|
| Outstanding at 1 January | 612,000 | EUR 9.70 | – | – |
| Granted during the year | 336,150 | EUR 6.68 | 612,000 | EUR 9.70 |
| Forfeited during the year | (75,025) | EUR 9.40 | – | – |
| Exercised during the year | – | – | – | – |
| **Outstanding at 31 December** | **873,125** | **EUR 7.41** | **612,000** | **EUR 9.70** |

| | 2022 Number | 2022 WAEP |
|---|---|---|
| Exercisable at 31 December | 143,089 | EUR 9.70 |

The weighted average remaining contractual life for the share options outstanding at 31 December 2022 was 9.2 years (2021: 10 years).

The weighted average fair value of options granted during the year was EUR 3.69 (2020: EUR 4.89).

The range of exercise prices for options outstanding at the end of the year was EUR 5.70 to EUR 9.70 (2021: EUR 9.70).

The fair value of the awarded options was determined by applying a Binomial Option Pricing Model that allows for exercising of the option before the end of the option's life.

As the Options cannot be exercised between the Grant Date and the vesting date, the Hull-White binomial formula, commonly used to value American options, was used. With the Hull-White model the impact of a certain time-based event – such as a vesting period, or an early exercise – can be taken into account.

Due to the different vesting dates for the different tranches in the option we have calculated the unique option values per tranche according to each vesting date. The total option value per employee is then derived using a weighted average overall calculated option value for each vesting date.

The following parameters were used in the option model for the calculation of the fair value of the options as per each grant date:

| | 2022–09 | 2022–04 | 2021–12 |
|---|---|---|---|
| Fair value on date of measurement (EUR) | **3.19** | **4.18** | **4.89** |
| Share price (EUR) | **5.70** | **7.64** | **9.20** |
| Exercise price (EUR) | **5.70** | **7.64** | **9.70** |
| Expected volatility | **59.30%** | **59.20%** | **58.90%** |
| Term of the option | **4[a]** | **4[a]** | **4[a]** |
| Expected dividend | **-** | **–** | **–** |
| Risk-free interest rate | **2.1%** | **0.55%** | **-0.30%** |
| Time to expiration | **10** | **10** | **10** |

*a: Vesting period is 1 – 4 years and depends on the vesting date of the specific tranche.*

## 2.10 Income Tax

**Accounting Policy:**

**Current Income Tax**

Current income tax assets and liabilities for the current period are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted, at the reporting date in the countries where the Group operates and generates taxable income.

Current income tax relating to items recognized directly in equity is recognized in equity and not in the statement of profit or loss. Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

**Deferred Tax**

Deferred tax is provided using the liability method on temporary differences between the tax basis of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- When the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss
- In respect of taxable temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future

Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences and the carry forward of unused tax credits and unused tax losses can be utilized, except:

- When the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.
- In respect of deductible temporary differences associated with investments in subsidiaries, associates and interests in joint ventures, deferred tax assets are recognized only to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are reassessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

**Significant Estimate:** The Group has losses before tax which arose in the Netherlands that are available to offset against future profits of the Dutch entity in which the loss arose. However, these losses may not be used to offset taxable income elsewhere in the Group. The Group evaluated and judged that at this moment it is not sufficiently likely that future profits will be generated in the Dutch entity that can offset a deferred tax asset.

All Switzerland operations have a cost-plus agreement. The taxable amounts are settled. There are no NOL's. Last fiscal year settled is 2020. Due to expected profits based on the cost-plus the Swiss deferred tax assets relating to temporary differences have been recognized.

All NOL's in the US entity prior to the business combination are not carried forward due to ownership change. Losses since the transaction can be carried forward for 20 years. These losses have not been recognized in the balance sheet to date.

All NOL's in the US entity prior to 2018 can be carried forward for 20 years. NOL's after 2018 can be carried forward indefinitely limited to 80% of taxable income. On the acquisition of ONWARD Medical Inc. (formerly knows as NRT Technologies) a deferred tax liability was recognised for the intangible asset (In-process R&D) identified in the PPA. At the time of the PPA there was no certainty regarding the future potential of the technology acquired and based on the limited available NOL's no deferred tax asset was recognised. IAS 12 requires that a deferred tax asset should recognised for the carry forward of unused tax losses when there are suitable reversing taxable temporary differences regardless of an entity's expectations of future tax losses. In 2022 the Company reassessed the recoverability of the assessed losses. This resulted in the recognition of a deferred tax asset of EUR 987k in the US entity that offsets the deferred tax liability as allowed under IAS 12, with no impact on previously reported results.

| | 2022 | 2021 |
|---|---|---|
| Current income tax | (185) | (69) |
| Deferred income tax | 951 | – |
| **Total corporate income tax in profit and loss** | **766** | **(69)** |
| Current Income Tax charge at tax rate of 25.8% (2021:25%) | 8,653 | 8,561 |
| Tax rate differences in foreign jurisdictions | 139 | 54 |
| Non-deductible expenses | (433) | (3,293) |
| Non-recognized deferred tax asset on temporary differences | (111) | (67) |
| Net operating losses not recognised | (8,458) | (5,324) |
| Recognition of prior year deferred tax adjustments | 976 | – |
| | **766** | **(69)** |

The effective tax rate was 2.3% in 2022 (2021: -0.2%), which is lower than the statutory income tax rate of 25.8% (2021:25%) in the Netherlands. The difference is primarily due to the net operating losses and temporary differences for which no deferred tax asset can be recognized. The uncertainty is based on insufficient evidence of future sources of income to support the realization of a deferred tax asset due to the Company being loss-making with limited tax planning opportunities. In addition, there are non-deductible share-based payments in 2022 and the prior year adjustment recorded in 2022 based on the reassessment of the recoverability of losses in the US.

The difference between 2021 and 2022 relates to one-off items in 2021 related to the IPO, the prior year adjustment in 2022 and the difference in the amounts of non-recognised losses.

Recognized deferred tax assets and liabilities

| 2022 | Assets | Liabilities | Net |
|---|---|---|---|
| Intangible assets, including Goodwill | – | (1,656) | (1,656) |
| Right of use assets | – | (235) | (235) |
| Lease liability | 240 | – | 240 |
| Post-employment benefits | 157 | | 157 |
| Losses available for offset against future taxable income | 987 | – | 987 |
| Set-off of deferred tax | (1,221) | 1,221 | – |
| **Net deferred tax liability** | **163** | **(670)** | **(507)** |

| 2021 | Assets | Liabilities | Net |
|---|---|---|---|
| Intangible assets, including Goodwill | – | (1,991) | (1,991) |
| **Net deferred tax liability** | **–** | **(1,991)** | **(1,991)** |

| | 2022 | 2021 |
|---|---|---|
| Opening balance at January 1 | (1,991) | (1,343) |
| Recognized in profit & loss | 951 | – |
| Remeasurement (gain)/loss on actuarial gains and losses in OCI | (59) | – |
| Foreign currency translation difference | 26 | (78) |
| Addition | – | (570) |
| Reclassification | 566 | – |
| **Net deferred tax liability at December 31** | **(507)** | **(1,991)** |

Of estimated amount of tax losses carried forward and available as at 31 December 2022, a deferred tax asset of EUR 987k has been recognized to offset the reversal of temporary differences in the US. For the remaining unused operating losses in the Netherlands of EUR 91M (2021: EUR 63M) and in the US of EUR 11M (2021: EUR 11M) no deferred tax is recognized. These losses can be carried forward indefinitely subject to local tax rules except for approximately EUR 3.2M of losses in the US which can be carried forward for 20 years (ultimately by 2037).

The Company offsets tax assets and liabilities if it has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same tax authority.

The deferred tax liability initially arose on the acquisition of NeuroRecovery Technolgies, Inc ('NRT') (subsequently renamed to ONWARD Medical Inc.). In the current year the deferred tax impact on the acquired intangibles was reclassified. This reclassification has no impact on the result for the period or equity.

## 3. Non-Current Asset & Working Capital

### 3.0 Intangible Assets

| | 2022 | 2021 |
|---|---|---|
| Goodwill | 1,902 | 1,702 |
| In-Process R&D | 5,873 | 6,109 |
| License fees | 2,383 | 2,218 |
| **Net book value at December 31** | **10,158** | **10,029** |

**Goodwill**

**Accounting Policy:** Goodwill is initially measured at cost, being the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests, and any previous interest held, over the net identifiable assets acquired and liabilities assumed. If the fair value of the net assets acquired is in excess of the aggregate consideration transferred, the Group re-assesses whether it has correctly identified all of the assets acquired and all of the liabilities assumed and reviews the procedures used to measure the amounts to be recognized at the acquisition date. If the re-assessment

still results in an excess of the fair value of net assets acquired over the aggregate consideration transferred, then the gain is recognized in profit or loss.

After initial recognition, goodwill is measured at cost less any accumulated impairment losses. For the purpose of impairment testing, goodwill acquired in a business combination is, from the acquisition date, allocated to each of the Group's cash-generating units that are expected to benefit from the combination, irrespective of whether other assets or liabilities of the acquiree are assigned to those units.

Where goodwill has been allocated to a cash-generating unit and part of the operation within that unit is disposed of, the goodwill associated with the disposed operation is included in the carrying amount of the operation when determining the gain or loss on disposal. Goodwill disposed in these circumstances is measured based on the relative values of the disposed operation and the portion of the cash-generating unit retained.

| | 2022 | 2021 |
|---|---|---|
| Cost | 1,702 | 1,607 |
| Accumulated amortization | – | – |
| **Net book value at January 1** | **1,702** | **1,607** |
| Additions | – | – |
| Foreign currency translation difference | 200 | 95 |
| Amortization for the year | – | – |
| Impairments | – | – |
| Net change | 200 | 95 |
| Cost | 1,902 | 1,702 |
| Accumulated amortization | – | – |
| **Net book value at December 31** | **1,902** | **1,702** |

### In-Process R&D

**Accounting Policy:** The cost of in-process R&D acquired in a business combination is the fair value at the date of acquisition.

Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortization and accumulated impairment losses. Amortization of the asset begins when development is complete and the asset is available for use. It is amortized over the period of expected future benefit. Amortization is recorded in operating expenses. During the period of development, the asset is tested for impairment annually.

| | 2022 | 2021 |
|---|---|---|
| Cost | 6,261 | 5,370 |
| Accumulated changes | (152) | (152) |
| **Net book value at January 1** | **6,109** | **5,218** |
| Foreign currency translation difference | 334 | 321 |
| Additions | – | 570 |
| Reclassification (refer to note 2.10) | (570) | |
| Amortization for the year | – | – |
| Impairments | – | – |
| Net change | (236) | 891 |
| Cost | 6,025 | 6,261 |
| Accumulated changes | (152) | (152) |
| **Net book value at December 31** | **5,873** | **6,109** |

### License Fees

**Accounting Policy:** License fees for the exclusive right to certain patents, critical in the development of the ARC Therapies, are capitalized and measured at cost on initial recognition.

Following initial recognition of the license fees as an asset, the asset is carried at cost less any accumulated amortization and accumulated impairment losses. Amortization of the asset begins when development of the ARC Therapies (ONWARD R&D) is complete, and the asset is available for use. It is amortized over the period of expected future benefit. Amortization is recorded in operating expenses. During the period of development, the asset is tested for impairment annually.

| | 2022 | 2021 |
|---|---|---|
| Cost | 2,218 | – |
| Accumulated changes | | – |
| **Net book value at January 1** | **2,218** | **–** |
| Additions | 31 | 2,233 |
| Foreign currency translation difference | 134 | (15) |
| Amortization for the year | – | – |
| Impairments | – | – |
| Net change | 165 | 2,218 |
| Cost | 2,383 | 2,218 |
| Accumulated changes | – | – |
| **Net book value at December 31** | **2,383** | **2,218** |

### Impairment Assessment

The In-process R&D was acquired through the acquisition of GTX Medical SA (now ONWARD Medical SA) and the business combination with NRT Inc.(now ONWARD Medical Inc.). The value of the In-process R&D is contingent on the success of the FDA approval of the NRT product. In terms of the NRT acquisition agreement ONWARD also received, and assumed responsibility for, the exclusive license agreements with the Regents of the University of California ("UCLA") and the California Institute of Technology ("Caltech"). In terms of these agreements, the occurrence of the IPO triggered the change in ownership clauses and resulted in additional payments to be made. These payments, as well as the annual license fee payments, are recognized as a separate class of intangible assets.

As per the accounting policies above goodwill, in-process R&D and license fees are tested for impairment annually. ONWARD performed its annual impairment test at year end (consistent with the prior year) based on the most recent budgets and forecast calculations.

**Significant Estimates:**

Key assumptions used in the impairment test was the growth rate, and the rate for discounting the projected cash flows.

- Cash flows are based on the expectation of receiving FDA approval. Revenue is expected only towards the end of 2023, starting with rehabilitation first. Home use following in later years. Operating costs increases to support sales and marketing efforts as well as to maintain ongoing development and clinical research. Based on management's best estimate EBITDA will not be positive prior to 2028.
- Growth rate estimate: rate is based on published industry research.
- Discount rate: Discount rates represent the current market assessment of the risks specific to ONWARD. The discount rate calculation is based on the specific circumstances of the Group and is derived from its weighted average cost of capital (WACC). The WACC takes into account both debt and equity. The cost of equity is derived from the expected return on investment by the Group's investors. The cost of debt is based on the interest-bearing borrowings the Group is obliged to service.

The cash flow projections were determined using management's internal forecasts that cover an initial period from 2023 to 2029, after which a terminal value was calculated. Using projected cash flows covering a period of more than five years is not considered unusual for pre-commercial life-science companies. Due to long development timelines and regulatory approval requirements, it is not untypical for Companies in the industry to use a period that extends beyond five years. The values assigned to the key assumptions represent management's assessment of future expectations. ONWARD performed a sensitivity analysis and noted that a reasonable change in either the discount rate (to 20%) or terminal growth rate (to 0%), or both the discount rate (to 20%) and terminal growth rate (to 0%), would not cause the carrying amount to exceed its recoverable amount. Also, should the expected revenues towards the end of 2023 move out to 2024, this would still not cause the carrying amount to exceed its recoverable amount.

| | 2022 | 2021 |
|---|---|---|
| Discount rate | 14.3% | 9.22% |
| Terminal value growth rate | 1.70% | 1.70% |

## 3.1 Property, Plant & Equipment

**Accounting Policy:** Property, plant and equipment is stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Such cost includes the cost of replacing part of the property, plant and equipment and borrowing costs for long-term construction projects if the recognition criteria are met. When significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognizes such parts as individual assets with specific useful lives and depreciates them accordingly. Likewise, when a major inspection is performed, its cost is recognized in the carrying amount of the plant and equipment as a replacement if the recognition criteria are satisfied. All other repair and maintenance costs are recognized in profit or loss as incurred.

Property, plant and equipment transferred from customers is initially measured at the fair value at the date on which control is obtained.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets as follows:

- Office equipment 3 years
- Leasehold improvements 5 years

The useful life of leasehold improvements is the same or less than the lease term

An item of property, plant and equipment and any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising from de-recognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the income statement when the asset is derecognized.

The residual values, useful lives and methods of depreciation of property, plant and equipment are reviewed at each financial year end and adjusted prospectively, if appropriate.

**Cost**

| | Office Equipment | Leasehold Improvements | Total |
|---|---|---|---|
| At January 1, 2021 | 711 | – | 711 |
| Additions | 91 | – | 91 |
| **At December 31, 2021** | **802** | **–** | **802** |
| Additions | 121 | 265 | 386 |
| Disposals | – | | – |
| **At December 31, 2022** | **923** | **265** | **1,188** |

**Depreciation**

| | Office Equipment | Leasehold Improvements | Total |
|---|---|---|---|
| At January 1, 2021 | (463) | – | (463) |
| Depreciation for the year | (149) | – | (149) |
| **At December 31, 2021** | **(612)** | **–** | **(612)** |
| Depreciation for the year | (135) | (26) | (161) |
| **At December 31, 2022** | **(747)** | **(26)** | **(773)** |

**Net Book Value**

| | Office Equipment | Leasehold Improvements | Total |
|---|---|---|---|
| At December 31, 2021 | 190 | – | 190 |
| **At December 31, 2022** | **176** | **239** | **415** |

## 3.2 Right of Use Assets & Lease Liabilities

**Accounting Policy:** The Group assesses at contract inception whether a contract is, or contains, a lease. That is, if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

**Group as a Lessee**

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognizes lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

**Right-of-Use Assets**

The Group recognises right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and accumulated impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the initial measurement amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received.

Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease term and the estimated useful lives of the assets.

If ownership of the leased asset transfers to the Group at the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

**Lease Liabilities**

At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for terminating the lease, if the lease term reflects the Group exercising the option to terminate.

Variable lease payments that do not depend on an index or a rate are recognized as expenses (unless they are incurred to produce inventories) in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease

payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the lease payments (e.g., changes to future payments resulting from a change in an index or rate used to determine such lease payments) or a change in the assessment of an option to purchase the underlying asset. The Group's lease liabilities are included in Lease liabilities.

**Short-term leases and leases of low-value assets**

The Group applies the short-term lease recognition exemption to its short-term leases of office space (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered to be low value. Lease payments on short-term leases and leases of low-value assets are recognized as expense on a straight-line basis over the lease term.

**Right-of-Use Assets**

The Group entered into a 5-year lease for offices in Lausanne, Switzerland in November 2021. This lease is classified as a right of use asset. The initial office lease in Eindhoven ended in December 2022 and was classified as a right of use asset up to October 2022, when the Group entered into a short-term office lease starting November 2022. Since November the initial Eindhoven lease was treated as an onerous contract from 1 November 2022 to the end of the lease contract 31 December 2022.

Key movements relating to right-of-use assets are presented below:

| | 2022 | 2021 |
|---|---|---|
| **Net book value at January 1** | **2,190** | **149** |
| Additions | 90 | 2,220 |
| Depreciation for the year | (575) | (179) |
| Onerous lease contract | (24) | |
| **Net book value at December 31** | **1,681** | **2,190** |

The office building is leased for office space. The lease includes an extension option exercisable up to one year before the end of the non-cancellable lease term. The option to renew the lease is for an additional period of the same duration after the end of the contract term and are at the option of the Group as lessee. The Group has elected not to exercise the option and no new lease agreement has been entered into as replacement yet.

### Lease Liabilities

The maturity of the lease liability in relation to the office building is as follows:

| | 2022 | 2021 |
|---|---|---|
| **Balance as at January 1** | **2,214** | **198** |
| Less than one year | 427 | 473 |
| One to five years | 1,294 | 1,741 |
| More than five years | – | – |
| **Total lease liability** | **1,721** | **2,214** |

| | 2022 | 2021 |
|---|---|---|
| **Balance as at January 1** | **2,214** | **198** |
| Additions | 90 | 2,220 |
| Onerous lease contract | (26) | – |
| Interest accretion | 84 | 21 |
| Repayments | (641) | (225) |
| **Total lease liability** | **1,721** | **2,214** |

The incremental borrowing rate applied is 4% for the Lausanne office and was 6% for the Eindhoven office (High Tech Campus) that ended on 31 October 2022.

On 1 November 2022 the Group entered into a short-term office lease for 12 months for which the Group has elected not to recognise a right of use asset and lease liability. Amount recognised in relation to this short-term lease amounted to EUR 8.8k.

For the maturity analysis of the undiscounted cash flows, refer to note 4.3

## 3.3 Indirect Tax Receivables

The tax receivables consist of refundable VAT and are collectable within 12 months. The increase in the receivable is a direct result of an increase in activities and costs for which VAT can be claimed.

## 3.4 Other Current Assets

| | 2022 | 2021 |
|---|---|---|
| Advance payments | 905 | 1,347 |
| Grants and other receivable | 266 | 902 |
| Rental Guarantee | 285 | 297 |
| | **1,456** | **2,546** |

The Group has pledged EUR 285k (2021: EUR 297k) of its cash at banks to fulfil collateral requirements relating to the Lausanne office rental agreement. Advance payments mostly relate to D&O insurance prepaid for which the premium improved in 2022. In 2021 grants and other receivables included amounts receivable from the DARPA grant which was received in 2022.

## 3.5 Cash and Cash Equivalents and Fixed Term Deposits

**Accounting Policy:** Cash and short-term deposits in the statement of financial position comprise cash at banks and on hand and short-term deposits with a maturity of three months or less, that are readily convertible to a known amount of cash and subject to an insignificant risk of change in value.

For the purpose of the consolidated statement of cash flows, cash and cash equivalents consist of cash and short-term deposits as defined above, net of outstanding bank overdrafts as they are considered an integral part of the Group's cash management.

| | 2022 | 2021 |
|---|---|---|
| Cash at bank | 21,760 | 89,443 |
| Short-term deposits | 20,000 | – |
| **Cash and cash equivalents** | **41,760** | **89,443** |
| Fixed term deposits | 20,000 | – |
| | **20,000** | **–** |
| **Cash and cash equivalents and fixed term deposits** | **61,760** | **89,443** |

Cash at banks earns interest at floating rates based on daily bank deposit rates. Short-term deposits are made for varying periods of between one day and three months, depending on the immediate cash requirements of the Group, and earn interest at the respective short-term deposit rates.

Fixed term deposits represent deposits made for varying periods exceeding three months but less than 12 months from inception.

At December 31, 2022, the Group had no bank overdrafts. All cash is freely at the disposal of the company.

### 3.6 Trade Payables

Trade payables and accrued expenses are non-interest bearing and are normally settled on 30-90 day terms. The increase is a direct result of an increase in activities and costs and the timing of settlement.

### 3.7 Other Payables

The other payables can be broken down as follows:

| | 2022 | 2021 |
|---|---|---|
| Wage tax and social security | 466 | 126 |
| Grants received in advance | 1,328 | – |
| Bonus | 1,856 | 1,770 |
| Invoices to be received | 732 | 466* |
| Other | 1,284 | 1,672* |
| | **5,666** | **4,034** |

** 2021: An amount of EUR 306k has been reclassified from Other to Invoices to be received for better comparison.*

The increase in Other Payables is due to Grant amounts received in advance. Other includes an amount of EUR 801k relating to grants to be paid to subcontractors (2021: EUR 0) and accrued expenses that decreased due to timing factors.

## 4. Financing, Financial Risk Management & Financial Instruments

### 4.0 Issued Capital & Reserves

**Share Capital & Share Premium**

**Accounting Policy:** Ordinary shares are classified as share capital. Equity instruments are recorded at the proceeds received, net of direct issue costs.

The share premium represents the amount by which the fair value of the consideration received exceeds the nominal value of shares issued. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

The authorized share capital ("maatschappelijk kapitaal") amounts to EUR 12,225,000 divided into 50,937,500 Ordinary Shares and 50,937,500 Preferred Shares with a nominal value of EUR 0.12 each.

At 31 December 2022, 30,184,388 Ordinary Shares were issued (31 December 2021: 30,184,388 shares). All of the issued Ordinary Shares are fully paid-up and represent capital in the Company. No Shareholders have any voting rights different from any other Shareholder.

### Other Reserves

| | Currency Translation Differences | Stock Compensation Reserve | Conversion Option Preference Shares | Total Other Reserves |
|---|---|---|---|---|
| **Balance at January 1, 2021** | **(532)** | **3,671** | **14,794** | **17,933** |
| Conversion of preference share on IPO | – | – | (14,794) | (14,794) |
| Share based payment expense: EIP | – | 8,494 | – | 8,494 |
| Share based payments: EIP accelerated vesting | – | (12,165) | – | (12,165) |
| Share based payment expense: LTIP | – | 69 | – | 69 |
| Currency translation differences | 249 | – | – | 249 |
| **Balance at December 31, 2021** | **(283)** | **69** | **–** | **(214)** |
| Share based payment expense: LTIP | – | 1,691 | – | 1,691 |
| Currency translation differences | 602 | – | – | 602 |
| **Balance at December 31, 2022** | **319** | **1,760** | **–** | **2,079** |

### Currency Translation Reserve

Exchange gains and losses arising from the translation of the functional currency of foreign operations to the reporting currency of the parent are accounted for in this legal reserve. In the case of the sale of a participating interest, the associated accumulated translation differences are transferred to the profit and loss account and presented therein as part of the result on the sale.

The foreign currency translation reserve relates to the investment in United States.

### Stock Compensation Reserve

The stock compensation reserve is used to recognize the value of equity-settled share-based payments provided to employees, including key management personnel, as part of their remuneration.

## 4.1 Earnings Per Share (EPS)

**Accounting Policy:**Basic EPS is calculated by dividing the profit for the year attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year.

Diluted EPS is calculated by dividing the profit attributable to ordinary equity holders of the parent (after adjusting for interest on the convertible preference shares) by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares.

The objective of determining diluted EPS is to reflect the maximum possible dilutive effect arising from potential ordinary shares outstanding during the period. The Group is currently loss making and there are currently no anti-dilutive potential ordinary shares to be considered. Therefore, diluted EPS is disregarded for 2022. The share options granted under the LTIP (refer to Note 2.9) could have a potential dilutive effect in the future, but had no impact in 2022.

There have been no other transactions involving ordinary shares or potential ordinary shares between the reporting date and the date of authorization of these financial statements.

The following tables reflect the income and share data used in the EPS calculation:

### Profit (Loss) Attributable to Ordinary Shareholders

| | 2022 | 2021 |
|---|---|---|
| Profit (loss) for the year, attributable to equity holders of the parent | (32,772) | (34,314) |

### Weighted-Average Number of Ordinary Shares

| | 2022 Thousands | 2021 Thousands |
|---|---|---|
| Weighted average number of ordinary shares for basic EPS | **30,184** | **9,485** |

## 4.2 Financial Liabilities

**Accounting Policy:**

**Financial Instruments – Initial Recognition & Subsequent Measurement**

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity. Financial assets and financial liabilities are initially recognized when the Company becomes a party to the contractual provisions of the instrument.

**Financial Liabilities**

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, payables, or as derivatives designated as hedging instruments in an effective hedge, as appropriate. A financial liability is classified as FVPL if it is classified as held-for-trading, it is a derivative or it is designated as such on initial recognition. Financial liabilities at FVPL are measured at fair value and net gains and losses, including any interest expense, are recognized in profit or loss. Other financial liabilities are subsequently measured at amortized cost using the effective interest method. Interest expense and foreign exchange gains and losses are recognized in profit or loss. Any gain or loss on derecognition is also recognized in profit or loss

All financial liabilities are recognized initially at fair value and, in the case of liabilities at amortized cost , net of directly attributable transaction costs.

The Group's financial liabilities include trade payables, other payables, loans and borrowings.

For purposes of subsequent measurement, financial liabilities are classified in two categories:

- Financial liabilities at fair value through profit and loss
- Financial liabilities at amortized cost

***Financial liabilities at fair value through profit or loss ("FVPL")***

Financial liabilities at fair value through profit or loss include financial liabilities held for trading and financial liabilities designated upon initial recognition as at fair value through profit or loss.

Financial liabilities are classified as held for trading if they are incurred for the purpose of repurchasing in the near term. This category also includes derivative financial instruments entered into by the Group that are not designated as hedging instruments in hedge relationships as defined by IFRS 9. Separated embedded derivatives are also classified as held for trading unless they are designated as effective hedging instruments.

Gains or losses on liabilities held for trading are recognized in the statement of profit or loss.

Financial liabilities designated upon initial recognition at fair value through profit or loss are designated at the initial date of recognition, and only if the criteria in IFRS 9 are satisfied. The Group has not designated any financial liability as at fair value through profit or loss.

***Financial Liabilities at Amortized Cost***

This is the category most relevant to the Group. After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost using the effective interest rate ("EIR") method. Gains and losses are recognized in the profit or loss when the liabilities are derecognized as well as through the EIR amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortization is included as finance costs in the statement of profit or loss.

### Derecognition

A financial liability is derecognised when the obligation under the liability is discharged or cancelled or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability at fair value. The difference in the respective carrying amounts is recognised in the statement of profit or loss.

### Offsetting of Financial Instruments

Financial assets and financial liabilities are offset and the net amount is reported in the consolidated statement of financial position if there is a currently enforceable legal right to offset the recognized amounts and there is an intention to settle on a net basis, to realize the assets and settle the liabilities simultaneously. No offsetting is currently applied.

| | 2022 | 2021 |
|---|---|---|
| **Balance as at 31 December** | **12,565** | **11,451** |

| | Innovation Loan | Convertible Preference A Shares | Convertible Loan |
|---|---|---|---|
| **Balance as per January 1, 2021** | **10,410** | **31,407** | **–** |
| Loan amount received / preference shares issued | – | – | 30,000 |
| Interest / cumulative dividend accrued during the year | 1,041 | 3,266 | 1,122 |
| Conversion to ordinary shares - IPO | – | (34,673) | (31,122) |
| **Balance as per December 31, 2021** | **11,451** | **–** | **–** |
| Loan amount received | – | – | – |
| Interest accrued during the year | 1,205 | – | – |
| **Balance as per December 31, 2022** | **12,656** | **–** | **–** |

### Innovation Loan

On 5 February 2016, the Group was granted a loan from RVO NL (Dutch Government) of EUR 10M payable according a set payment scheme.

The loan carries interest at 10%.

The current redemption plan for the loan is as presented below:

| Date | % of Loan Amount |
|---|---|
| 1 January 2026 | 15.0 |
| 1 April 2026 | 15.0 |
| 1 July 2026 | 17.5 |
| 1 October 2026 | 17.5 |
| 1 January 2027 | 17.5 |
| 1 April 2027 | 17.5 |
| 1 July 2027 | All due interest |

Certain Intellectual Property (patents registered), have been pledged to the RVO NL in case of default of repayment of the loan. These patents have not been capitalized as at 31 December 2022.

### Convertible Preference A Shares

The convertible preference A shares carried a dividend of 6% per annum. The dividend rights were cumulative. The preference shares ranked ahead of the ordinary shares in the event of a liquidation. The preference A shares could be converted into Ordinary Shares of the company under different scenarios, where the rights and number of Ordinary Shares received differs. In the event of an IPO, conversion is mandatory at a fixed conversion rate of 1:1, subject to adjustments for any changes in the share capitalization of the Company.

As part of the corporate conversion (in 2021), all preference A shares were converted to Ordinary shares at a ratio of 1:1 based on the numbers of preference A shares. The mandatory conversion upon IPO was considered the maturity event for this instrument.

The carrying value of the financial liability was derecognised and recognised as equity (share premium reserve) The equity component of the conversion option (previously recognized in other reserves) was reclassified to share premium on conversion before the reversed stock split was affected on all ordinary shares and the nominal value increased to EUR 0,12 per share.

### Convertible Loan

On 20 April 2021 the Company entered into a Convertible Loan Agreement of EUR 30M, received in 2 instalments. The annual interest rate was 8%. The convertible loan was repayable within 36 months from date of signing the agreement. The repayment date was therefore 2024. The conversion option was considered an embedded derivative which is bifurcated and treated as a financial instrument at fair value through profit and loss. After the corporate conversion (in 2021) but immediately before the IPO the full loan amount, including contractual interest accrued converted into ordinary shares.

## 4.3 Financial Risk Management Objectives & Policies

The Group's principal financial liabilities comprise of loans and borrowings and trade and other payables. The main purpose of these financial liabilities is to finance the Group's operations and to provide guarantees to support its operations.

The Group is responsible for implementing and evaluating policies which govern the funding, investments and any use of derivative financial instruments. The Group is exposed to various risks. The Group monitors risk exposure on an ongoing basis, as summarized below:

### Capital Management

Capital includes issued capital, convertible preference shares, share premium and all other equity reserves attributable to the equity holders of the parent. The primary objective of the Group's capital management is to continue as a going concern while maximising shareholder value. The Group manages its capital structure and will consider adjustments in light of changes in economic conditions. To maintain or adjust the capital structure, the Group may issue new shares.

### Liquidity Risk

The Group manages liquidity risk by continuously monitoring forecast and actual cash flows. The Group's objective is to maintain a balance between continuity of funding and flexibility through the use of subsidies and grants, and sufficient progress towards regulatory approval, which is related to future financing rounds.

Cash is invested in low-risk investments such as short-term bank deposits or savings accounts. The Group mainly makes use of liquid investment in current accounts (in Euro) or short-term deposit accounts. The ability of the Group to maintain adequate cash reserves to support its activities in the medium term is highly dependent on the Group's ability to raise additional funds.

The following table details the undiscounted remaining contractual maturity for the Group's financial liabilities with agreed repayment periods, including both interest and principal cash flows:

As of 31 December 2022:

| | Less than 1 Year | 1-3 Years | 3-5 Years | More than 5 Years | Total |
|---|---|---|---|---|---|
| Innovation loan | – | – | 19,298 | – | 19,298 |
| Lease liability | 512 | 1,452 | – | – | 1,964 |
| Trade payables | 1,909 | – | – | – | 1,909 |
| **Total** | **2,421** | **1,452** | **19,298** | **–** | **23,171** |

As of 31 December 2021:

| | Less than 1 Year | 1-3 Years | 3-5 Years | More than 5 Years | Total |
|---|---|---|---|---|---|
| Innovation loan | – | – | 6,500 | 12,798 | 19,298 |
| Lease liability | 490 | 1,470 | 408 | – | 2,368 |
| Trade payables* | 952 | – | – | – | 952 |
| **Total** | **1,442** | **1,470** | **6,908** | **12,798** | **22,618** |

** This line has been restated from prior year to only include trade payables.*

### Market Risk

Market risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market prices. The Group's activities may expose it to changes in foreign currency exchange rates and interest rates. The Group is not exposed to any equity price risk or commodity price risk as it does not invest in these classes of investments.

### Credit Risk

Because of the absence of sales to third parties and therefore trade receivables, credit risk arises mainly from cash and cash equivalents and deposits with banks and financial institutions. The Group only works with international reputable commercial banks and financial institutions when investing surplus funds. Short – and fixed term deposits are subject to approval in line with internal policy. The Group holds accounts with ING, Belfius, UBS, First American Bank, Deutsche Bank and Banque Cantonale Vaudoise (BCV). The number of banks and financial institutions is to minimise concentration risk and therefore mitigate financial loss through a counterparty's potential failure to make payments.

### Currency Risk

Currency risk is the risk that reported financial performance, or the fair value or future cash flows of a financial instrument, will fluctuate because of changes in foreign exchange rates. The Group is exposed to currency risk for the activities mainly in the US as the accounting is performed in US dollars whereas the functional currency of the Group is the euro. The risk is currently managed by replenishing the US bank account at regular intervals to account for both the positive and negative changes.

## 4.4 Fair Value & Fair Value Hierarchy of the Financial Statements

**Accounting Policy:** All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 — Quoted (unadjusted) market prices in active markets for identical assets or liabilities
- Level 2 — Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable
- Level 3 — Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

The carrying amounts and fair values of the Group's financial instruments are as follows, including its fair value hierarchy:

| 2022 | Carrying Amount | Estimated Fair Value |
|---|---|---|
| **Financial liabilities** | | |
| Innovation credit loan (Level 2) | 12,656 | 13,689 |
| **Total financial liabilities** | **12,656** | **13,689** |

| 2021 | Carrying Amount | Estimated Fair Value |
|---|---|---|
| **Financial liabilities** | | |
| Innovation credit loan (Level 2) | 11,451 | 13,218 |
| **Total financial liabilities** | **11,451** | **13,218** |

Management has assessed that the fair values of cash and cash equivalents, accounts payable, taxes and social securities and other payables approximate to their carrying amounts largely due to the short-term maturities of these instruments.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale. The following methods and assumptions were used to estimate the fair values:

The fair value of Innovation credit loan and due interest have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities.

During the period, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

### 4.5 Financial Expense

**Accounting Policy:** Interest income is recognized by applying the effective interest rate, except for short-term receivables when the effect of discounting is immaterial. The Company's financial assets include cash and cash equivalents and other long term and current receivables.

Borrowing costs directly attributable to the acquisition, construction or production of an asset that necessarily takes a substantial period of time to get ready for its intended use or sale are capitalized as part of the cost of the asset. All other borrowing costs are expensed in the period in which they occur. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

| | 2022 | 2021 |
|---|---|---|
| Interest income from deposits | 62 | – |
| Interest on loans | (1,205) | (5,430) |
| Interest post-employment benefits | - | 1 |
| Interest banks | (226) | (146) |
| Interest on lease liabilities | (84) | (21) |
| Exchange losses | (24) | (100) |
| Bank charges | (33) | (17) |
| **Net Finance expense** | **(1,510)** | **(5,713)** |

## 5. Other Disclosures

### 5.0 Post-Employment Benefits: Defined Benefit Obligation

**Accounting Policy:** Group companies operate various pension schemes. The schemes are funded through payments to insurance companies or trustee-administered funds, determined by periodic actuarial calculations. The Group has both defined benefit and defined contribution plans.

**Defined Benefit Plan**

The Group operates a defined benefit pension plan in Switzerland, which requires contributions to be made to a separately administered fund. The cost of providing benefits under the defined benefit plan is determined using the projected unit credit method.

Remeasurements, comprising of actuarial gains and losses are recognised in the statement of financial position with a corresponding debit or credit to retained earnings through OCI in the period in which they occur. Remeasurements are not reclassified to profit or loss in subsequent periods.

Past service costs are recognised in profit or loss on the earlier of:

- The date of the plan amendment or curtailment, and
- The date that the Group recognises related restructuring costs

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset. The Group recognises the changes in the net defined benefit obligation due to service costs comprising current service costs, past-service costs, gains and losses on curtailments and non-routine settlements as part of operating expenses and the net interest expense or income as part of net finance costs in the consolidated statement of profit and loss.

| | 2022 | 2021 |
|---|---|---|
| Plan assets | 3,879 | 1,756 |
| Obligation | (5,001) | (3,144) |
| **Net liability** | **1,121** | **1,388** |

A defined benefit plan is a pension plan that is not a defined contribution plan. Typically, defined benefit plans specify an amount of pension benefit that an employee will receive upon retirement, typically dependent on one or more factors such as age, years of service and compensation. The benefits paid to employees in Switzerland qualify as a defined benefit plan.

The pension plan for Swiss employees ("the Pension Fund") is a defined benefit plan. The Pension Fund provides benefits for retirement, disability and surviving dependents that meet or exceed the minimum benefits required under the Federal Law on Occupational Retirement, Survivors' and Disability Insurance ("BVG"), including the legal coordination charge, which is also insured. The monthly premium to fund the Pension Fund's benefits is split equally between the employer and the employees. Contributions, which vary by the age of the employees, range from 6-13% of the covered salary and are credited to the employees' individual retirement savings accounts. The Pension Fund is responsible for capital investments and pursues an investment strategy with a prescribed investment policy. The Group assumes an average retirement age of 62 (female) and 63 (male), respectively. Upon retiring (including early and partial retirement), insured persons are entitled to a lifelong retirement pension if employees do not choose to withdraw the entire balance, or portion thereof, of their individual retirement savings accounts in the form of a capital payment.

The Pension Fund is administered by Allianz Suisse, Switzerland, which is legally separate from the Group and is governed by a foundation board. In addition, there is a pension fund commission comprised of two employee and two employer representatives. The duties of the foundation board, as well as the pension fund commission, are laid out in the BVG and the specific pension fund rules. They are required by law to act in the best interest of the participants and are responsible for setting certain policies (e.g. investment, contribution and indexation policies) for the Pension Fund. At least four times a year, the foundation board, as well as the pension fund commission, meet to analyze consequences and decide on adjustments in the investment strategy.

Pursuant to the BVG, additional employer and employee contributions may be imposed whenever a significant funding deficit arises in accordance with the BVG. In addition to investment risk, the Pension Fund is exposed to actuarial risk, longevity risk, currency risk and interest rate risk.

In addition to the pension plan for Swiss employees, a defined benefit plan for Swiss management also provides retirement benefits and risk insurance for death and disability for components of remuneration in excess of the maximum insurable amount of salary under the plan described above.

**Movement of Net Defined-Benefit Liability**

| | 2022 | 2021 |
|---|---|---|
| **Balance as at January 1** | **1,388** | **399** |
| Service costs | 562 | 167 |
| Admin costs | 43 | 14 |
| Past service costs | – | 264 |
| Employee benefit expenses | 605 | 445 |
| Net interest costs / (income) | 3 | (1) |
| ***Included in statement of profit and loss*** | ***608*** | ***444*** |
| Actuarial gains / (losses) | | |
| – Financial assumptions | (1,956) | (94) |
| – Demographic assumptions | – | – |
| – Experience adjustment | 1,286 | 727 |
| – Return on assets excluding interest income | 184 | 81 |
| | (486) | 714 |
| Exchange rate differences | 65 | 30 |
| ***Included in statement of comprehensive income*** | ***(421)*** | ***744*** |
| **Contributions by employer** | **(454)** | **(199)** |
| **Balance as at December 31** | **1,121** | **1,388** |

The principal assumptions used in determining post-employment (pension) benefit obligations for the plan are shown below:

| | 2022 | 2021 |
|---|---|---|
| Discount rate | 2,30% | 0,30% |
| Salary increase | 2,50% | 2,50% |
| Interest credit rate | 1,00% | 0,60% |
| Mortality base table | BVG2020 | BVG2020 |
| Longevity improvement | CMI2018; 1,25% | CMI2018; 1,25% |

A quantitative sensitivity analysis for significant assumptions as at 31 December is shown below:

| | 2022 | 2021 |
|---|---|---|
| Discount rate | | |
| + 25bps | (190) | (147) |
| - 25bps | 203 | 159 |
| Salary increase | | |
| + 25bps | 84 | 102 |
| - 25bps | (80) | (62) |
| Interest credit rate | | |
| + 25bps | 76 | 30 |
| - 25bps | (73) | (29) |
| Mortality base table | | |
| Life expectancy + 1 year | 27 | 35 |
| Life expectancy - 1 year | (26) | (33) |

The sensitivity analyses have been determined based on a method that extrapolates the impact on the defined benefit obligation as a result of reasonable changes in key assumptions occurring at the end of the reporting period. The sensitivity analyses are based on a change in a significant assumption, keeping all other assumptions constant. The sensitivity analyses may not be representative of an actual change in the defined benefit obligation as it is unlikely that changes in assumptions would occur in isolation from one another.

The following are the expected payments or contributions to the defined benefit plan in future years:

| | 2022 | 2021 |
|---|---|---|
| Within the next 12 months | 281 | 123 |
| Between 2 and 5 years | 1,426 | 640 |
| Beyond 5 years | 2,540 | 1,428 |
| **Total expected payments** | **4,247** | **2,191** |

The average duration of the defined benefit plan obligation at the end of the reporting period is 16 years (2021: 19 years).

**Plan Assets Allocation**

The asset allocation in the Swiss pension plan at December 31 was as follows:

| | 2022 | 2021 |
|---|---|---|
| Bonds | 2,309 | 1,004 |
| Equities | – | 168 |
| Loans | 134 | 52 |
| Mortgages | 504 | 207 |
| Real Estate | 872 | 300 |
| Cash, derivatives and funds | 60 | 25 |
| | **3,879** | **1,756** |

Plan assets in 2022 do not include property occupied by or financial instruments issued by ONWARD.

## 5.1 Commitments & Contingencies

### Legal Claim Contingencies

As at December 31, 2022, the Group had no legal claim contingencies.

### Guarantees

The Group has provided a guarantee to Wincasa for EUR 273k and EUR 8k to SPACES as collateral for the lease of the office spaces.

### Royalties

The Group has entered into three license agreements with EPFL that will pay out royalties in case the Company is able to generate revenues in the future for products directly linked to these licenses. The royalty scheme with EPFL is based on net sales. To date no royalties have been paid as there is no product generating revenue.

On 27 September 2019 Neurorecovery Technologies Inc. (now ONWARD Medical Inc.) entered into a license agreement with the Regents of the University of California acting through Technology Development Group UCLA campus granting an exclusive license on certain patents in certain fields of neuromodulation and spinal cord stimulation and a non-exclusive license on certain other patent rights. Various revenue milestone payments are due under the exclusive license and fixed royalty payments are due under the non-exclusive license. The agreement contains various milestone and diligence obligations ranging from USD 10k to USD 50k payable upon entering a phase III clinical trial, regulatory approval and/or first commercial sale. To date none of the milestones triggering the obligations have occurred.

On 8 October 2019 Neurorecovery Technologies Inc. (now ONWARD Medical Inc.) entered into a license agreement with the California Institute of Technology ("Caltech"), the latter on behalf of various intellectual property owners, including UCLA, University of Louisville, DEI and USC, granting an exclusive license on certain technology in certain fields of epidural and transcutaneous neuromodulation and a non-exclusive license of certain other intellectual property. Various revenue milestone payments, diligence obligations and fixed royalty payments are due under the license. These payments range from USD 20k to USD 75k payable upon FDA approval, CE Mark and/or first commercial sale. To date no payments are due as none of the requirements have been met.

## 5.2 Related Party Transactions

Note 1.2 provides the information about the Group's structure including the details of the subsidiaries. Transactions between the Company and its subsidiaries have been eliminated on consolidation and are not disclosed in the notes.

The Group considers the board and the management team to be key management as defined in IAS 24 'Related parties'. Full details of the remuneration of the board (CEO and non-executives) are included in the Remuneration report.

| 2022 | Salary, Bonuses & Other (Short-Term Employee Benefits) | Pension Premiums (Post-Employment Eenefits) | Share-Based Payment | Total |
|---|---|---|---|---|
| Management team, excluding CEO | 2,574 | 105 | 596 | 3,275 |
| CEO | 917 | 44 | 469 | 1,430 |
| Non-executive directors | 364 | – | 256 | 621 |
| | **3,855** | **149** | **1,321** | **5,326** |

| 2021 | Salary, Bonuses & Other (Short-Term Employee Benefits) | Pension Premiums (Post-Employment Eenefits) | Share-Based Payment | Total |
|---|---|---|---|---|
| Management team, excluding CEO | 2,073 | 78 | 2,164 | 4,315 |
| CEO | 1,163 | 28 | 2,140 | 3,331 |
| Non-executive directors | 436 | – | 1,180 | 1,616 |
| | **3,672** | **106** | **5,484** | **9,261** |

## 5.3 Events After the Reporting Period

After 31 December 2022 the Group granted 968,250 stock options to the Management team, including the CEO and CSO with an exercise price of EUR 6.12. The conditions of the existing plan as explained in Note 2.9 applies to this grant.

# Company Statement of Income

For the Year Ended 31 December

| *All amounts in EUR '000* | Notes | 2022 | 2021 |
|---|---|---|---|
| **Grants** | | **2,076** | **1,219** |
| **Total operating income** | **B** | **2,076** | **1,219** |
| General and administrative expenses | | (31,003) | (27,254) |
| **Total operating expenses** | **C** | **(31,003)** | **(27,254)** |
| **Operating result for the period** | | **(28,927)** | **(26,035)** |
| Net Finance expense | **D** | (1,453) | (5,662) |
| **Result before tax** | | **(30,380)** | **(31,697)** |
| Income tax expense | | **–** | **–** |
| Share in result from participating interests | **E** | **(2,392)** | **(2,617)** |
| **Result after tax** | | **(32,772)** | **(34,314)** |

The notes on pages **290** to **299** are an integral part of these separate financial statements.

# Company Balance Sheet

*(Before appropriation on result)*

For the Year Ended 31 December

| *All amounts in EUR '000* | Notes | 2022 | 2021 |
|---|---|---|---|
| **Assets** | | | |
| **Non-current assets** | | | |
| Tangible fixed assets | F | 61 | 197 |
| Financial fixed assets | G | 1,139 | 2,459 |
| | | 1,200 | 2,656 |
| **Current assets** | | | |
| Trade and other receivables | H | 16,900 | 7,846 |
| Fixed term deposits | I | 20,000 | – |
| Cash at bank and in hand | I | 31,501 | 88,777 |
| | | 68,401 | 96,623 |
| | | 69,601 | 99,279 |

| | | | |
|---|---|---|---|
| **Equity & Liabilities** | | | |
| **Equity and reserves** | J | | |
| Issued capital | | 3,622 | 3,622 |
| Share premium | | 155,249 | 155,249 |
| Other reserves | | 1,760 | 69 |
| Legal reserve: Currency translation differences | | 319 | (283) |
| Retained earnings | | (75,547) | (41,660) |
| Result for the year | | (32,772) | (34,314) |
| **Total equity** | | 52,631 | 82,683 |
| **Provisions** | K | 256 | 214 |
| **Non-current liabilities** | L | 12,656 | 11,451 |
| **Current liabilities** | M | 4,058 | 4,931 |
| | | 69,601 | 99,279 |

The notes on pages **290** to **299** are an integral part of these separate financial statements.

# Notes to the Company Financial Statements

## A. Presentation of Financial Statements and Recognition and Measurement Principles

The description of the activities of ONWARD Medical NV (the company) and the company structure, as included in the notes to the consolidated financial statements, also applies to the company financial statements.

These separate financial statements have been prepared in accordance with Title 9, Book 2 of the Dutch Civil Code. For setting the principles for the recognition and measurement of assets and liabilities and determination of results for its separate financial statements, the Company makes use of the option provided in section 2:362(8) of the Dutch Civil Code. This means that the principles for the recognition and measurement of assets and liabilities and determination of the result (hereinafter referred to as principles for recognition and measurement) of the separate financial statements of the Company are the same as those applied for the consolidated EU-IFRS financial statements. These principles also include the classification and presentation of financial instruments, being equity instruments or financial liabilities. In case no other principles are mentioned, refer to the accounting principles as described in the consolidated financial statements. For an appropriate interpretation of these statutory financial statements, the separate financial statements should be read in conjunction with the consolidated financial statements.

Information on the use of financial instruments and on related risks for the group is provided in the notes to the consolidated financial statements of the group.

## B. Operating Income

Operating income relates to grant and other income received. Government subsidies have been received for the research and development of several development projects. There are no unfulfilled conditions or contingencies attached to these subsidies.

| | 2022 | 2021 |
|---|---|---|
| Government subsidies (EU) | 1,972 | 1,219 |
| Other income | 104 | – |
| **Total revenues and other income** | **2,076** | **1,219** |

| | | Recognized | |
|---|---|---|---|
| **Grants** | **Total Grant*** | **2022** | **2021** |
| BESTABLE | **100** | **–** | **16** |
| PREP2GO | **348** | **104** | **139** |
| DARPA | **3,172** | **1,412** | **981** |
| ZonMW | **250** | **83** | **83** |
| EISMEA – Reverse Paralysis | **1,228** | **273** | **–** |
| EISMEA - NEMO BMI | **1,020** | **85** | **–** |
| Eurostars Impulse | **500** | **14** | **–** |
| **Total** | | **1,972** | **1,219** |

## C. Operating Expenses

Operating expenses by nature are as follows:

| | 2022 | 2021 |
|---|---|---|
| Employee benefits | (5,277) | (12,122) |
| Other operating expenses | (25,515) | (14,909) |
| Depreciation | (211) | (223) |
| | **(31,003)** | **(27,254)** |

The increase in Other operating expenses is driven by Research and Development expenses due to advancements made on our ARC$^{EX}$ and ARC$^{IM}$ platforms (mainly in Switzerland) which increased the charge from Switzerland to the Netherlands under the existing agreement.

Employee benefits includes share-based payment expense for all employees located in The Netherlands, Switzerland and the United States. As of 31 December 2022, the Company had 16.3 full-time equivalents located in the Netherlands (2021: 35.5), 68.3 full-time equivalents located in Switzerland (2021: 32.9) and 11.5 (2021: 8.5) full-time equivalents located in the United States. The 2021 expense includes the accelerated vesting of the Employee Investment Plan.

## D. Net Finance Expense

| | 2022 | 2021 |
|---|---|---|
| Interest income | 52 | – |
| Interest on loans | (1,434) | (5,430) |
| Interest banks | – | (146) |
| Interest on lease liabilities | – | (7) |
| Exchange losses | (48) | (65) |
| Bank charges | (23) | (14) |
| **Net Finance expense** | **(1,453)** | **(5,662)** |

The decrease is the result of the conversion of the preference A shares and the convertible loan in 2021 that no longer exist in 2022.

## E. Share in Results from Participating Interests

An amount of EUR 2.392M (2021: EUR 2.617M) of share in results from participating interests relates to group companies.

## F. Tangible Fixed Assets

### Cost

| | Office Equipment | Total |
|---|---|---|
| At January 1, 2021 | 1,116 | 1,116 |
| Additions | 55 | 55 |
| **At December 31, 2021** | **1,171** | **1,171** |
| Additions | 10 | 10 |
| Disposals | (465) | (465) |
| **At December 31, 2022** | **716** | **716** |

### Depreciation

| | Office Equipment | Total |
|---|---|---|
| At January 1, 2021 | (751) | (751) |
| Depreciation for the year | (223) | (223) |
| **At December 31, 2021** | **(974)** | **(974)** |
| Depreciation for the year | (102) | (102) |
| Disposal | 421 | 421 |
| **At December 31, 2022** | **(655)** | **(655)** |

**Net Book Value**

| | Office Equipment | Total |
|---|---|---|
| **At December 31, 2021** | **197** | **197** |
| **At December 31, 2022** | **61** | **61** |

## G. Financial Fixed Assets

Financial fixed assets consist of participating interests in group companies. Financial fixed assets are accounted for in the Company financial statements at net asset value. They are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount.

| | 2022 | 2021 |
|---|---|---|
| Cost | 2,459 | 3,102 |
| Accumulated impairments | – | – |
| **Net book value at 1 January** | **2,459** | **3,102** |
| Revaluations through OCI | 858 | (714) |
| Exchange differences | 172 | 255 |
| Share in result of participating interests | (2,392) | (2,617) |
| Addition: License fees paid on behalf of subsidiary | – | 2,219 |
| Provision: negative participating interest | 42 | 214 |
| Net change | (1,320) | (643) |
| Cost | 1,139 | 2,459 |
| Accumulated impairments | – | – |
| **Net book value at 31 December** | **1,139** | **2,459** |

The Company has the firm intention to support its subsidiary, ONWARD Medical SA, to meet its obligations to third parties. A provision has been recognised for the negative value of the investment to the amount of EUR 1.199k (2021: 214k).

## H. Trade & Other Receivables

Amounts due from group companies are recognized initially at fair value and subsequently at amortized cost. Amortized cost is determined using the effective interest rate. The company recognize a credit loss for financial assets (such as a loan) based on an expected credit loss (ECL) which will occur in the coming twelve months or – after a significant decrease in credit quality or when the simplified model can be used – based on the entire remaining loan term.

For intercompany receivables the ECL would be applicable as well, however this could cause differences between equity in the consolidated and separate financial statements. For this reason, the company elected to eliminate these differences through the respective receivable account in the separate financial statements.

| | 2022 | 2021 |
|---|---|---|
| Indirect tax receivable | 458 | 290 |
| Receivables from related parties – group companies | 15,174 | 5,492 |
| Receivables from related parties – other | 190 | – |
| Other | 257 | 820 |
| Advance payments made | 821 | 1,244 |
| | **16,900** | **7,846** |

The Company funds the operations of the subsidiaries. The increase in the receivable is a result of the increase in operations in 2022.

## I. Cash at Bank, in Hand & Fixed Term Deposits

| | 2022 | 2021 |
|---|---|---|
| Cash at bank | 21,501 | 88,777 |
| Short-term deposits | 10,000 | – |
| Cash at bank and in hand | **31,501** | **88,777** |
| Fixed term deposits | 20,000 | – |
| | **20,000** | **–** |
| Cash at bank, in hand and fixed term deposits | **51,501** | **88,777** |

Cash at banks earns interest at floating rates based on daily bank deposit rates. Short-term deposits are made for varying periods of between one day and three months, depending on the immediate cash requirements of the Group, and earn interest at the respective short-term deposit rates. Fixed term deposits are made for period exceeding three months but less than one year and earn interest at the respective fixed term deposit rates

At December 31, 2022, the Group had no bank overdrafts. All cash is freely at the disposal of the company.

## J. Shareholders' Equity

For the statement of changes in equity for the year ended 31 December 2022, please refer to Consolidated statement of changes in equity in the consolidated financial statements. Additional information on the shareholders' equity is disclosed in note 4.0 of the consolidated financial statements.

## K. Provisions

| | 2022 | 2021 |
|---|---|---|
| Opening balance as at 1 January | 214 | – |
| Negative participating interest | 42 | 214 |
| **Balance as at 31 December** | **256** | **214** |

## L. Non-Current Liabilities

| | 2022 | 2021 |
|---|---|---|
| **Balance as at 31 December** | **12,656** | **11,451** |

| | 2022<br>Innovation Loan |
|---|---|
| **Loan as per 1 January** | **11,451** |
| Loan amount received | - |
| Interest / cumulative dividend accrued during the year | 1,205 |
| **Net book value at 31 December** | **12,656** |

## M. Current Liabilities

Amounts due to group companies recognized as financial liabilities at amortized cost as per the policy in the consolidated financial statements.

| | 2022 | 2021 |
|---|---|---|
| Trade payables | 1,962 | 464 |
| Payables from related parties | – | 2,358 |
| Other payables | 2,096 | 2,109 |
| | **4,058** | **4,931** |

## N. Compensation of the Board Of Directors

The members of the Board and the Management Team are considered key management personnel as defined in IAS 24 'Related party disclosures'. For details on their remuneration, reference is made to note 5.2 of the consolidated financial statements. Full details of the remuneration of the board (CEO and non-executives) are included in the Remuneration report.

## O. Fees for Audit & Other Services

In accordance with article 382.a of Part 9, Book 2, of the Netherlands Civil Code, the total audit cost can be specified as follows:

**Ernst & Young Accountants LLP**

| | 2022 | 2021 |
|---|---|---|
| Audit of financial statements | 478 | 180 |
| Audit of special purpose financial statements | – | 679 |
| Other assurance services | 8 | 39 |
| | **486** | **898** |

## P. Subsequent Events

For subsequent events, please refer to Note 5.3 of the Consolidated Financial Statements.

## Q. Proposed Appropriation of Result

The Board of Directors proposes to deduct the net loss in full to the retained earnings.

# Independent Auditor's Report

# Other Information

To: the shareholders and board of directors of ONWARD Medical N.V.

**Report on the audit of the financial statements 2022 included in the annual report**

**Our Opinion**

We have audited the financial statements 2022 of ONWARD Medical N.V. based in Amsterdam, the Netherlands.

The financial statements comprise the consolidated and company financial statements.

In our opinion:

- the accompanying consolidated financial statements give a true and fair view of the financial position of ONWARD Medical N.V. as at 31 December 2022 and of its result and its cash flows for 2022 in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code
- the accompanying company financial statements give a true and fair view of the financial position of ONWARD Medical N.V. as at 31 December 2022 and of its result for 2022 in accordance with Part 9 of Book 2 of the Dutch Civil Code

The consolidated financial statements comprise:

- the consolidated statement of financial position as at 31 December 2022.
- the following statements for 2022: the consolidated statements of profit and loss, comprehensive income, changes in equity and cash flows
- the notes comprising a summary of the significant accounting policies and other explanatory information.

The company financial statements comprise:

- the company balance sheet as at 31 December 2022
- the company statement of income for 2022
- the notes comprising a summary of the accounting policies and other explanatory information.

**Basis for Our Opinion**

We conducted our audit in accordance with Dutch law, including the Dutch Standards on Auditing. Our responsibilities under those standards are further described in the Our responsibilities for the audit of the financial statements section of our report.

We are independent of ONWARD Medical N.V. ('the company') in accordance with the EU Regulation on specific requirements regarding statutory audit of public-interest entities, the "Wet toezicht accountantsorganisaties" (Wta, Audit firms supervision act), the "Verordening inzake de onafhankelijkheid van accountants bij assurance-opdrachten" (ViO, Code of Ethics for Professional Accountants, a regulation with respect to independence) and other relevant independence regulations in the Netherlands. Furthermore we have complied with the "Verordening gedrags- en beroepsregels accountants" (VGBA, Dutch Code of Ethics).

We believe the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

**Information in Support of Our Opinion**

We designed our audit procedures in the context of our audit of the financial statements as a whole and in forming our opinion thereon. The following information in support of our opinion and any findings were addressed in this context, and we do not provide a separate opinion or conclusion on these matters.

***Our Understanding of the Business***

ONWARD Medical N.V. and its subsidiaries (the 'group') are developing both an Implantable Neuro-stimulation Systems (INS) and a non-invasive system for electrical stimulation of specific areas of the spinal cord.

We determined materiality and identified and assessed the risks of material misstatement of the financial statements, whether due to fraud or error in order to design audit procedures responsive to those risks and to obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion.

**Materiality**

| | |
|---|---|
| **Materiality** | €890,000 (2021: €1,100,000) |
| **Benchmark applied** | 3% of operating expenses |
| **Explanation** | R&D companies such as ONWARD Medical N.V. which are in the start-up phase, report no or modest revenues. The stakeholders expect the entity to operate at a loss during the R&D phase. The value that owners or others generally attribute to these entities is primarily based on the promise of future success of the products. Based on these factors we deem operating expenses to be a suitable basis, as it is one of the most important measures of the company's performance. |

We have also taken into account misstatements and/or possible misstatements that in our opinion are material for the users of the financial statements for qualitative reasons.

We agreed with the audit committee of the board of directors that misstatements in excess of €44,500 which are identified during the audit, would be reported to them, as well as smaller misstatements that in our view must be reported on qualitative grounds.

***Scope of the Group Audit***

ONWARD Medical N.V. is at the head of a group of entities. The financial information of this group is included in the consolidated financial statements.

Because we are ultimately responsible for the opinion, we are also responsible for directing, supervising and performing the group audit. In this respect we have determined the nature and extent of the audit procedures to be carried out for group entities. Decisive were the size and/or the risk profile of the group entities or operations. On this basis, we selected group entities for which an audit or review had to be carried out on the complete set of financial information or specific items.

The processes of Onward Medical are highly centralized and all transactions are initiated, recorded, processed and reported on central level. We have applied a centralized audit approach and all audit procedures are performed by the same team.

In total these procedures represent 100% of the group's total assets, operating expenses and net loss.

By performing the centralized procedures mentioned above at all components of the group, together with additional procedures at group level, we have been able to obtain sufficient and appropriate audit evidence about the group's financial information to provide an opinion on the consolidated financial statements.

***Teaming & Use of Specialists***

We ensured that the audit team included the appropriate skills and competences which are needed for the audit of a listed client in the medical technology industry. We included specialists in the areas of IT audit, forensics, share based payments, valuation of intangible assets, actuaries and income tax.

***Our Focus on Fraud and Non-Compliance With Laws and Regulations***

**Our Responsibility**

Although we are not responsible for preventing fraud or non-compliance and we cannot be expected to detect non-compliance with all laws and regulations, it is our responsibility to obtain reasonable assurance that the financial statements, taken as a whole, are free from material misstatement, whether caused by fraud or error. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

**Our Audit Response Related to Fraud Risks**

We identified and assessed the risks of material misstatements of the financial statements due to fraud. During our audit we obtained an understanding of the company and its environment and the components of the system of internal control, including the risk assessment process and management's process for responding to the risks of fraud and monitoring the system of internal control and how the board of directors exercises oversight, as well as the outcomes.

We refer to section "Risk Management & Control" of the management report for management's (fraud) risk assessment.

We evaluated the design and relevant aspects of the system of internal control and in particular the fraud risk assessment, as well as the code of conduct. We evaluated the design and the implementation of internal controls designed to mitigate fraud risks.

As part of our process of identifying fraud risks, we evaluated fraud risk factors with respect to financial reporting fraud, misappropriation of assets and bribery and corruption in close co-operation with our forensic specialists. We evaluated whether these factors indicate that a risk of material misstatement due to fraud is present.

We incorporated elements of unpredictability in our audit. We also considered the outcome of our other audit procedures and evaluated whether any findings were indicative of fraud or non-compliance.

As in all of our audits, we addressed the risks related to management override of controls. For these risks we have performed procedures among others to evaluate key accounting estimates for management bias that may represent a risk of material misstatement due to fraud, in particular relating to important judgment areas and significant accounting estimates as disclosed in Note 1.6 to the financial statements including research & development, share-based payments, impairment of intangible assets, post-employment benefits and income taxes. We have also used data analysis to identify and address high-risk journal entries and evaluated the business rationale (or the lack thereof) of significant extraordinary transactions, including those with related parties. These risks did however

not require significant auditor's attention. Furthermore we note that we did not identify a risk of fraud in revenue recognition.

We considered available information and made enquiries of relevant executives and directors.

Our fraud risk assessment, enquiries and other available information did not lead to specific indications for fraud or suspected fraud potentially materially impacting the view of the financial statements.

**Our Audit Response Related to Risks of Non-Compliance With Laws and Regulations**

We performed appropriate audit procedures regarding compliance with the provisions of those laws and regulations that have a direct effect on the determination of material amounts and disclosures in the financial statements. Furthermore, we assessed factors related to the risks of non-compliance with laws and regulations that could reasonably be expected to have a material effect on the financial statements from our general industry experience, through discussions with management, reading minutes and performing substantive tests of details of classes of transactions, account balances or disclosures.

We also inspected lawyers' letters and we have been informed by management that there was no correspondence with regulatory authorities . We remained alert to any indication of (suspected) non-compliance throughout the audit. Finally we obtained written representations that all known instances of non-compliance with laws and regulations have been disclosed to us.

***Our Audit Response Related to Going Concern***

Management made a specific assessment of the company's ability to continue as a going concern and to continue its operations for the foreseeable future). As disclosed in Note 1.4 to the financial statements the Company believes that its cash position will be sufficient to meet the Company's capital requirements and fund its operations for at least 12 months as from the date of this Annual report. Furthermore is stated that to continue development and reach commercialization as planned the Company will need to attract additional funds in the future and that the Company's long term existence is contingent on achieving FDA approval and CE mark on its products. The financial statements have been prepared on a going concern basis.

We discussed and evaluated the specific assessment with management exercising professional judgment and maintaining professional skepticism. We considered whether management's going concern assessment, based on our knowledge and understanding obtained through our audit of the financial statements or otherwise, contains all relevant events or conditions that may cast significant doubt on the company's ability to continue as a going concern.

Based on our procedures performed, we did not identify material uncertainties about going concern at least 12 months as from the date of this Annual report. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company to cease to continue as a going concern.

***Our Key Audit Matters***

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements. We have communicated the key audit matters to the board of directors (including the non-executive members forming the audit committee). The key audit matter is not a comprehensive reflection of all matters discussed.

In comparison with previous year, the nature of our key audit matter did not change.

### Valuation of intangible fixed assets

**Note 3.0 intangible assets**

**Risk**

At year-end 2022, ONWARD Medical N.V. carried an intangible asset balance of € 10.2 million, consisting of goodwill (€ 1.9 million), capitalized in-process R&D (€ 5.9 million) and capitalized license fees (€ 2.4 million). The goodwill as well as the capitalized in-process R&D and license fees relate to the acquisition of ONWARD Medical Inc in 2019. In accordance with EU-IFRS, ONWARD Medical N.V. is required to perform an impairment test on an annual basis. The impairment test is significant to our audit because the assessment process is complex, requires management judgement, and is based on assumptions that are affected by expected future market conditions. For these reasons, we consider this a key audit matter.

**Our audit approach**

As part of our audit procedures we audited the assumptions and methodologies used by the company, and also the robustness of the planning process to evaluate whether the company is able to prepare reliable estimates.

The value of the in-process R&D is contingent on the success of the US Food and Drug Association (FDA) approval and CE mark of the company's products, as well as successfulness of bringing the products to the market.

In order to assess the reasonability of input data, the valuation model and the discount rate we have, among other procedures:

- verified the appropriateness and consistent application of the impairment model and related inputs;
- compared the data with external data such as expected inflation rate, external market growth expectations and market capitalization of the Company;
- analyzed the sensitivities in the company's impairment testing model.

We specifically focused on the risk of not achieving regulatory approvals and whether a reasonable possible change in the assumptions could trigger an impairment.

We also evaluated the adequacy of the company's disclosure in note 3.0 of the annual report, including disclosures regarding assumptions and sensitivities as well as consistency between the going concern forecasts as disclosed in Note 1.4 and the inputs in the company's impairment testing model.

**Key observations**

We have evaluated management's key assumptions and estimates to be within an acceptable range. We agree with management's conclusion that no impairment of intangible assets is required and conclude that the disclosures in note 3.0 of the annual report are appropriate.

**Report on Other Information Included in the Annual Report**

The annual report contains other information in addition to the financial statements and our auditor's report thereon.

Based on the following procedures performed, we conclude that the other information:

- is consistent with the financial statements and does not contain material misstatements
- contains the information as required by Part 9 of Book 2 of the Dutch Civil Code for the Board of Directors' report and the other information as required by Part 9 of Book 2 of the Dutch Civil Code and as required by Sections 2:135b and 2:145 sub section 2 of the Dutch Civil Code for the remuneration report.

We have read the other information. Based on our knowledge and understanding obtained through our audit of the financial statements or otherwise, we have considered whether the other information contains material misstatements. By performing these procedures, we comply with the requirements of Part 9 of Book 2 and Section 2:135b sub-Section 7 of the Dutch Civil Code and the Dutch Standard 720. The scope of the procedures performed is substantially less than the scope of those performed in our audit of the financial statements.

The board of directors is responsible for the preparation of the other information, including the Board of Directors' report in accordance with Part 9 of Book 2 of the Dutch Civil Code and other information required by Part 9 of Book 2 of the Dutch Civil Code. The board of directors is responsible for ensuring that the remuneration report is drawn up and published in accordance with Sections 2:135b and 2:145 sub section 2 of the Dutch Civil Code.

**Report on Other Legal and Regulatory Requirements and ESEF**

***Engagement***

We were engaged by the general meeting as auditor of ONWARD Medical N.V. on 11 October 2021, as of the audit for the year 2021 and have operated as statutory auditor ever since that date.

***No Prohibited Non-Audit Services***

We have not provided prohibited non-audit services as referred to in Article 5(1) of the EU Regulation on specific requirements regarding statutory audit of public-interest entities.

***European Single Electronic Reporting Format (ESEF)***

ONWARD Medical N.V. has prepared the annual report in ESEF. The requirements for this are set out in the Delegated Regulation (EU) 2019/815 with regard to regulatory technical standards on the specification of a single electronic reporting format (hereinafter: the RTS on ESEF).

In our opinion, the annual report prepared in the XHTML format, including the partially marked-up consolidated financial statements as included in the reporting package by ONWARD Medical N.V. complies in all material respects with the RTS on ESEF.

The board of directors is responsible for preparing the annual report, including the financial statements, in accordance with the RTS on ESEF, whereby the board of directors combines the various components into a single reporting package.

Our responsibility is to obtain reasonable assurance for our opinion whether the annual report in this reporting package complies with the RTS on ESEF.

We performed our examination in accordance with Dutch law, including Dutch Standard 3950N 'Assurance-opdrachten inzake het voldoen aan de criteria voor het opstellen van een digitaal verantwoordingsdocument' (assurance engagements relating to compliance with criteria for digital reporting). Our examination included amongst others:

- obtaining an understanding of the company's financial reporting process, including the preparation of the reporting package
- identifying and assessing the risks that the annual report does not comply in all material respects with the RTS on ESEF and designing and performing further assurance procedures responsive to those risks to provide a basis for our opinion, including:
  - obtaining the reporting package and performing validations to determine whether the reporting package containing the Inline XBRL instance document and the XBRL extension taxonomy files, has been prepared in accordance with the technical specifications as included in the RTS on ESEF
  - examining the information related to the consolidated financial statements in the reporting package to determine whether all required mark-ups have been applied and whether these are in accordance with the RTS on ESEF.

**Description of Responsibilities Regarding the Financial Statements**

**Responsibilities of the Board of Directors for the Financial Statements**

The board of directors is responsible for the preparation and fair presentation of the financial statements in accordance with EU-IFRS and Part 9 of Book 2 of the Dutch Civil Code. Furthermore, the board of directors is responsible for such internal control as the board determines is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to fraud or error.

As part of the preparation of the financial statements, the board of directors is responsible for assessing the company's ability to continue as a going concern. Based on the financial reporting framework mentioned, the board of directors should prepare the financial statements using the going concern basis of accounting unless the board either intends to liquidate the company or to cease operations, or has no realistic alternative but to do so. The board of directors should disclose events and circumstances that may cast significant doubt on the company's ability to continue as a going concern in the financial statements.

The non-executive board members of the board of directors are responsible for overseeing the company's financial reporting process.

**Our Responsibilities for the Audit of the Financial Statements**

Our objective is to plan and perform the audit engagement in a manner that allows us to obtain sufficient and appropriate audit evidence for our opinion.

Our audit has been performed with a high, but not absolute, level of assurance, which means we may not detect all material errors and fraud during our audit.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements. The materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

We have exercised professional judgment and have maintained professional skepticism throughout the audit, in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. The 'Information in support of our opinion' section above includes an informative summary of our responsibilities and the work performed as the basis for our opinion.

Our audit further included among others:

- Performing audit procedures responsive to the risks identified, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion
- Obtaining an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control
- Evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management
- Evaluating the overall presentation, structure and content of the financial statements, including the disclosures
- Evaluating whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation

***Communication***

We communicate with the audit committee of the board of directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant findings in internal control that we identify during our audit.

In this respect we also submit an additional report to the audit committee of the board of directors in accordance with Article 11 of the EU Regulation on specific requirements regarding statutory audit of public-interest entities. The information included in this additional report is consistent with our audit opinion in this auditor's report.

We provide the audit committee of the board of directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the audit committee of the board of directors, we determine the key audit matters: those matters that were of most significance in the audit of the financial statements. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, not communicating the matter is in the public interest.

**Eindhoven, 27 March 2023**

**Ernst & Young Accountants LLP**

**Signed by J.C.F. Lemmens**

## Profit Appropriation

Pursuant to the Articles of Association, the profits shown in the Company's annual accounts in respect of a financial year shall be appropriated as follows, and in the following order of priority:

- to the extent that any preferred shares have been cancelled without full repayment as described in the articles of association and without any such deficit subsequently having been paid in full, an amount equal to any such (remaining) deficit shall be distributed to those who held those preferred shares at the moment of such cancellation becoming effective;
- to the extent that any Preferred Distribution (or part thereof) in relation to previous financial years has not yet been paid in full as described in the articles of association, an amount equal to any such (remaining) deficit shall be distributed on the preferred shares;
- the Preferred Distribution shall be distributed on the preferred shares in respect of the financial year to which the annual accounts pertain;
- the Board shall determine which part of the remaining profits shall be added to the Company's reserves; and
- subject to a proposal by the board of directors to that effect, the remaining profits shall be at the disposal of the General Meeting for distribution on the ordinary shares.

## Special Statutory Voting Rights

There are no special statutory voting rights.

## Shares Carrying Limited Economic Entitlement

The preferred shares in the Company's capital carry a limited entitlement to the Company's profit and reserves. At 31 December 2022, no preferred shares in the Company's capital were issued.

## Branches

The Company has no branches. The statutory list of all subsidiaries and affiliated companies, prepared in accordance with the relevant legal requirements (Netherlands Civil Code, Part 9 of Book 2, Sections 379 and 414), forms part of the notes to the consolidated financial statements.

## Non-IFRS Financial Measure

This Annual Report contains a financial measure that is not a measure of liquidity under IFRS. This is commonly referred to as non-IFRS financial measure.

Although the non-IFRS financial measure presented is not a measure of liquidity under IFRS, the company uses this measure to monitor the underlying performance of its business and operations. This measure has not been audited or reviewed by the company's external auditor. Furthermore, the measures may not be indicative of the company's historical operating results, nor is this measure meant to be predictive of the company's future results. This measure is presented in this Annual Report because the company considers it an important supplemental measure for evaluating the company's liquidity.

### *Net Cash*

Net cash is defined as the sum of cash and cash equivalents and fixed term deposits included in the current assets as included in consolidated statement of financial position in the Financial Statements.

The company discloses the following as net cash for the measurement and explanation of liquidity:

| | 2022 | 2021 |
|---|---|---|
| Cash at bank | 21,760 | 89,443 |
| Short-term deposits | 20,000 | – |
| Cash and cash equivalents | **41,760** | **89,443** |
| Fixed term deposits | 20,000 | – |
| | **20,000** | **–** |
| **Net cash** | **61,760** | **89,443** |

## Definitions & Abbreviations

The following definitions are used in this report:

**510(k)**
Clearance under Section 510(k) of the FDCA

**AIS**
ASIA impairment scale

**ASIA**
American Spinal Injury Association

**BDD**
Breakthrough Device Designation - Designation given by the FDA to allow a timely access to devices providing a more effective treatment or diagnosis of life-threatening diseases by speeding-up their development, assessment and review

**Brain Spine Interface**
Electrical signal produced by the brain is recorded and translated into a signal allowing the stimulation of the spine in a timely manner

**Caltech**
California Institute for Technology

**Cardiovascular**
Relating to the heart and blood vessels

**CARF**
Commission of Accredited Rehabilitation Facilities

**CE**
Conformité Européene

**Cervical**
Relating to the neck or located around the neck area

**CGC**
The Dutch corporate governance code issued on 8 December 2016

**Chairperson**
The Chairperson of the Board

**CHUV**
Centre Hospitalier Universitaire Vaudois

**CRO**
Contract research organisations

**CSO**
Chief Scientific Officer

**DARPA**
The US Department of Defense Advanced Research Projects Agency

**DSMB**
Data Safety Monitoring Board

**EBITDA**
Earnings before interest, tax, depreciation and amortization

**EEA**
European Economic Area

**EPFL**
École Polytechnique Fédérale de Lausanne

**Epidural**
Placed or administered outside the dura mater

**Eurostar Grants**
A grant from the Eurostars Programme of EUREKA together with the European Community, named Prep2Go

**FDA**
U.S. Food and Drug Administration

**FDCA**
U.S. Federal Food, Drug, and Cosmetic Act

**FTE**
Full time equivalent personnel

**GCP**
Good Clinical Practice

**HDE**
Humanitarian Device Exemption

**Hemodynamics**
Forces involved in blood circulation in the body

**HIPAA**
Health Insurance Portability and Accountability

**HUD**
Humanitarian use device

**Hypertension**
Higher blood pressure than normal range

**Hypotension**
Lower blood pressure than normal range

**IPG**
ONWARD implantable pulse generator

**Lesion**
A damaged region in the body

**LTIP**
Long-Term Incentive Plan

**Lumbar**
Relating to the lumbar region of the back

**MDR**
Medical Device Regulation

**Medical Devices Regulation**
Regulation (EU) 2017/745

**MHRA**
Medicines and Healthcare products Regulatory Agency

**Neurodegenerative**
Characterized by the degeneration of the nervous system

**Neuromodulation**
Field of bioengineering implicating technologies impacting neural interfaces

**Neuroprosthetic**
Device used to restore function in the body via the interface of electrodes and the nervous system.

**Neurostimulation**
Application of an electrical stimulation inducing modulation or activation of the nervous system for a therapeutic effect

**Neurorehabilitation**
Supervised program of training to restore function to patients who suffered from a neurological disorder.

**NHS**
National Health Service – in the United Kingdom: refers to the publicly funded healthcare systems

**Orthostatic hypotension**
Hypotension caused by transition to an upright position

**Paraplegic**
Someone affected by paralysis (partial or complete) of the lower half of the body due to an injury or disease of the spinal cord.

**Perfusion**
Passage of a fluid (blood, water) through blood vessels, tissue or organ

**PMA**
Pre-market approval

**QSR**
Quality System Regulations

**Reeve Foundation**
Christopher and Dana Reeve Foundation

**RVO**
Rijksdienst voor Ondernemend Nederland

**Scaffold (cellular)**
Scaffolds engineered to induce cellular interactions contributing to the formation of new functional tissues

**SCI**
Spinal Cord Injury – damage to the nerves in the spine that circulate signals from the brain to and from the body. It can be caused by a trauma or a disease. This damage can lead to temporary or permanent dysfunctions.

**Sensorimotor paralysis**
Condition that decreases the ability of a person to feel and move due to a nerve damage

**Spasticity**
Abnormal increase in muscle tone usually caused by nerve damage and can be associated with pain

**STIMO**
STImulation Movement Overground (title of clinical study)

**Tetraplegic (Quadraplegic)**
Someone affected by paralysis (partial or complete) of upper and lower limbs due to injury or disease of the spinal cord.

**Thoracic**
Related to the thoracic region of the back

**Transcutaneous**
Penetrating through the skin. For example: transcutaneous stimulation is stimulation delivered through the skin via electrodes placed on the skin

**UCLA**
University of California, Los Angeles

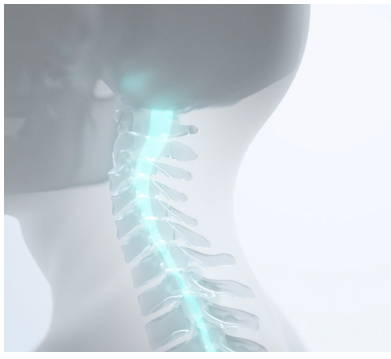
**Up-LIFT**
Pivotal study to evaluate the Company's ARC$^{EX}$ Therapy

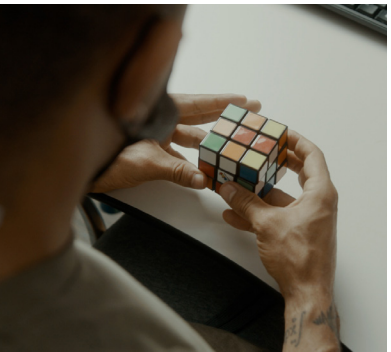
**Vascular**
Relating to blood vessels

**ZonMw grant**
A grant from ZonMw

ONWARD

Forward to **2023**



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